# EXHIBIT C2

# UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO ALL CASES

MDL NO. 16-2738 (FLW) (LHG)

AMENDED RULE 26 EXPERT REPORT OF ROBERT B. COOK, PHD

Date: January 22, 2019

Robert B. Cook, PhD

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The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. My opinions are as follows:

# I. QUALIFICATIONS

I received an EM degree in Mining Engineering from The Colorado School of Mines (1966) and M.S. (1968) and Ph.D. (1971) degrees in Geology from the University of Georgia. I worked in the mineral exploration industry for several years before beginning an academic career at Auburn University. At Auburn I was a full Professor, member of the Graduate Faculty, and the Department of Geology Graduate Program Officer and later Department Head for 22 years. While there I acted in a consulting capacity for the United Nations (Technical Advisor program to the PRC), NASA, the Department of Defense, and the U.S. Department of Justice. I am a registered geologist in Alabama, Georgia, and Florida. I have authored the state mineralogies for Alabama and Georgia These describe every mineral that occurs within the particular state. The mineralogies both describe mineral deposits containing talc, asbestos, and heavy metals. I have also authored approximately 100 research-based publications, and an equal number of published abstracts of papers given before learned societies. As a part of my professional experience, I have explored the mineralogy and consulted with mining companies regarding the exploration for and mineralogy of talc deposits. My curriculum vitae is attached to this report as Exhibit A.

### II. SUMMARY OF OPINIONS

I have been asked to review the geology of the talc deposits that sourced Defendants' talcum powder products, to evaluate the mining practices employed, and to assess Defendants' sampling and testing from a mining perspective. The opinions expressed in this report are rendered with a reasonable degree of scientific certainty. Based on my education, training, and experience in the fields of mining and geology and my review of the relevant information for this matter, I have reached the following conclusions and opinions:

- A. Talc deposits derived by the alteration of serpentinites contain chrysotile and amphibole species in fibrous asbestiform habits, all of which are known carcinogens.
- B. Fibrous talc occurs in serpentinite-derived talc deposits, possibly by pseudomorphism of early chrysotile or amphiboles. Such fibrous talc is not detectable by standard amphibole asbestos XRD screening used by Defendants nor would it be entirely removed during the milling process. Fibrous talc fulfills the requirements for inclusion with asbestiform minerals which are known to be human carcinogens.
- C. Mine development and selective mining are not completely effective in avoiding ore and ore-related rock potentially containing amphiboles, chrysotile, and elevated amounts of certain heavy metals and arsenic.

- D. Sampling and screening techniques for amphibole asbestos used by the Defendants<sup>1</sup> are inadequate to detect asbestiform amphiboles at levels below one tenth of one percent. Therefore, meeting a "none detected" standard does not mean that there is no asbestos present in the material. In some instances, testing methodologies employed by Johnson & Johnson or required of its suppliers or consultants were inadequate.
- E. Talc from Vermont deposits used by Defendants for its talcum powder products have elevated nickel (Ni) and cobalt (Co) as trace constituents by substitution for magnesium (Mg). Elevated amounts of nickel, cobalt, chromium and relatively small amounts of arsenic (As) can occur associated with Vermont talc deposits as constituents of accessory minerals that include chlorite family species, sulfides, arsenides, and oxides. Analytical data indicate that nickel, chromium and cobalt, known or probable carcinogens, reach finished talc products in amounts above Johnson & Johnson's (J&J) specified limits.
- F. Sampling for quality control purposes from 1965 to the present has not been shown to result in data representative of mine sites, ore lots, or processing facilities. Sampling frequency and methodology are inconsistent; blending and poor documentation often sever the traceability of sample to origin; and sample sizes are not representative of the whole of the product.
- G. The value of quarterly and annual composite samples to evaluate talc ore and talcum powder for asbestos and heavy metals is inadequate. The data indicate that in some instances analytical results were not received in a timely manner and provisions for quarantine of out-of-spec product were inadequate, resulting in product containing asbestos and excessive amount of heavy metals continuing to be released to market.

# III. GENERAL DISCUSSION AND OPINIONS

Certain aspects of mining, processing, mineralogy, geochemistry, sampling, and testing of talc when used for personal hygiene and cosmetic purposes are discussed in this report. In preparation, I reviewed the following: results of my professional experience examining talc and related mineral occurrences, my experience with optical examination of drill core<sup>2</sup> and commercial rock products for asbestos and other related minerals, the published literature, and documents produced in this litigation. The list of materials I considered is attached as Exhibit B.

<sup>&</sup>lt;sup>1</sup> Since 1989, Imerys Talc America, Inc. ("Imerys") or one of its predecessor companies have supplied talc to Johnson & Johnson for its talcum powder products. These predecessor companies include Cyprus Talc Corporation, Luzenac America, Inc., and Rio Tinto Group. Throughout this report, these entities should be considered synonymous with Imerys.

<sup>&</sup>lt;sup>2</sup> Though I have adequate data and materials upon which to base my opinions, I have requested the opportunity to inspect the drill cores obtained at the Vermont mines. The analysis of drill cores is a generally accepted method for evaluating a geological deposit. It is my understanding that Imerys has refused to make the drill cores available.

#### A. MINING AND PROCESSING

Talc is a mineral that has been used for a wide variety of purposes including cosmetics and personal hygiene. It is a very soft, flexible magnesium silicate with the general formula Mg<sub>3</sub>Si<sub>4</sub>O<sub>10</sub>(OH)<sub>2</sub> and may occur in a variety of forms (massive or platy, foliated and fibrous). Talc deposits form in a variety of ways, often by the alteration of pre-existing rocks of appropriate composition. Talc deposits of significance to this litigation are generally of two types: first, those associated with altered ultramafic rocks or serpentinites (Vermont) and second, ores formed from the alteration of, or otherwise associated with, dolomitic carbonates (Italy and China).

Talc deposits can contain asbestos<sup>3</sup>, asbestiform minerals, or minerals containing elevated levels of heavy metals and arsenic, making their ores potentially unsafe. The distribution of asbestos and/or these undesirable elements can be quite irregular within individual talc deposits themselves or their immediately adjacent host rocks. This makes the delineation of ore bodies, variations in physical and chemical parameters within them, and their mining and processing difficult from a quality control standpoint. Sampling protocols and analytical techniques that fully ensure acceptable quality control are themselves equally challenging. To determine suitability for use in body powder, talc ores should be carefully evaluated for mineralogy (including the presence or absence of asbestos); grindability; microbial content; color; odorant retention and stability; bulk density; particle size, shape, and distribution; major and trace element chemistry.

# i. Chronology of Talc Sources

From 1926 through the mid-1960's, J&J utilized talc for its talcum powder products which was mined from a sequence of altered dolomitic marbles located in Italy's Chisone valley district.<sup>4</sup> Talc ore produced from this region was referred to by J&J as Grade EGT EXTRA 00000 or 1615 AGIT talc, the source or sources of this historical cosmetic talc were deposits associated with highly deformed marble-bearing schists of the Dora-Maira sequence in the Piedmont region west of Torino. The geology of the famous Fontane mine of the district has recently been described (including maps) by Cadoppi and others (2016). Earlier (1955) descriptions of the district and its mines are given in JNJAZ55\_000000597. Deposits from this region are known to be mineralogically complex, particularly with respect to their host metamorphics. Historical testing documents indicate that these deposits contain both fibrous amphiboles and fibrous talc. The deposits were often small and mined by underground methods.

In 1963, Eastern Magnesia Talc Company developed a method to produce cosmetic talcum powder products from ore found in a deposit located at Hammondsville, Vermont.<sup>5</sup> Beginning in approximately 1965, J&J began to use talc originating from Vermont in its talcum powder

<sup>3</sup> Asbestos is the generic designation for a group of naturally occurring mineral silicate fibers of the serpentine and amphibole series. These include the serpentine mineral chrysotile and the five amphibole minerals – actinolite, amosite, anthophyllite, crocidolite, and tremolite (IARC, 1973; USGS, 2001; IARC 2012). IARC classifies asbestos as a human carcinogen (IARC, 1987; IARC, 2012).

<sup>4</sup> Use of the Italian ore was stopped or significantly reduced during World War II. During the years approximately 1941 through 1945, talc for J&J talcum powder products was mined from California. (JNJAZ55 000000049).

<sup>&</sup>lt;sup>5</sup> For general geographic orientation, a Vermont state map showing the locations of some of the major talc facilities as they existed in 1989 may be seen in Downey Exhibit 48.

products. The first comprehensive overview of Vermont's talc deposits was given by Chidester, Billings, and Cady in 1951 and a review of the ultramafic province of Vermont including its serpentinite-associated talc and asbestos deposits was published in Ratte (1982). The consanguinity of talc and asbestos in such deposits is further supported by the numerous descriptions of both talc and asbestos in deposits such as Bain (1934; 1942). The intimate association of amphiboles including those of asbestiform habit with talc deposits derived from serpentinites and related rocks is discussed by Van Gosen (2004).

By 1968, Johnson & Johnson purchased Eastern Magnesia Talc Company which subsequently became Windsor Minerals. By the early 1970's, Italian talc destined for American markets was all but eliminated by this domestic source. Talc used by Johnson & Johnson for body powders was produced from the following Vermont mines from about 1965 to 2003: Johnson, Hammondsville, Hamm, Rainbow, and Argonaut.

Initially, Vermont talc mines were underground with open pit operations becoming more common in the 1980's. A good example of this progression is documented for the Argonaut mine (JNJ 000348020). Full face continuous mining machines were used in the underground mines, similar to those used in some coal and potash mines. More traditional stoping<sup>6</sup> was initiated a few years later to increase production. Open pit mining began in 1979 utilizing both the continuous mining machines and traditional drilling and blasting techniques. Underground mining ceased there in 1980. The Argonaut east orebody was developed in the early 1990's and supplied ore to the West Windsor mill for the production of Grade 66 talc. Johnson & Johnson's Grade 66 talc was produced by each of these mining methods at different times.

From 1986 to 1991, Argonaut ore was blended with both Hammondsville and Hamm mine ores to produce J & J Grade 66 talc. An overview of mining methods utilized at the Argonaut mine is found in a 2002 Luzenac report. (Ex. 24; Downey deposition). Other descriptions of the Argonaut open pit operations are in the 2008 Argonaut mine annual report (IMERYS 441340), and a 2005 consulting report by Golder Associates (IMERYS 501883). There is ample evidence that the main and east Argonaut ore bodies are segments of the same ore body swarm, making them and talc ore derived from them essentially equivalent.

The Johnson mine, as well as the Hammondsville, Hamm, Rainbow, and Argonaut mines exploited talc deposits that are closely associated with serpentinite bodies. Asbestos minerals including chrysotile, actinolite, tremolite, and anthophyllite occur in talc-bearing serpentinites. Talc processing was carried out at plants located in Windsor and nearby Ludlow, Vermont. Other plants in operation in the early 1990's include those at Chester and Johnson, Vermont although the material was sold as industrial grade talc (IMERYS 132823).

In 2003, Imerys started sourcing talc for J&J's talcum powder products from the Guangxi province of China (Grade 25). Chinese talc occurrences, including those in Guangxi province, have been described in certain Imerys documents (IMERYS 416973, IMERYS 196407, and IMERYS 413792). These reports indicate that the talc was extracted from the Jhizhua mine, Longsheng County. The talc deposit at the Jhizhua mine is derived from the alteration of a relatively pure dolomitic marble found in the upper Proterozoic Hetong Formation. The deposit is

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<sup>&</sup>lt;sup>6</sup> Stoping is the process of extracting or removing the desired ore or other mineral from an underground mine, leaving behind an open space.

large and exploited by open pit mining methods. The location of the Chinese talc sources can be seen on maps accompanying references cited above. Hand sorting at the mine is used as a first step in the beneficiation process. The ore is then imported and processed in an Imerys central plant in Houston, Texas.<sup>7</sup>

# ii. Mining and Talc Composition

For mining operations producing tens of thousands of tons of ore annually for cosmetic or personal hygiene purposes as in this case, careful controls should be employed to assure the uniformity and purity of talc in terms of grade, mineralogy, and trace element chemistry. Initially, deposits are delineated by core drilling at a spacing between holes that can vary from a few tens of feet in unusual cases to grids on 100-foot centers, or wider. Regardless of spacing, rock between drill holes is assumed or interpreted to be of a certain quality based on the geologist's evaluation of the core from the nearest holes and observations from outcrops. This can result in a good general delineation of the ore body but one that requires periodic revision or refining as mining progresses into areas between widely spaced core holes or other data points.

Drill core is typically about two inches in diameter, and while adequate for primary ore determination and analyses, it is not representative of trace constituents for areas between core holes. This is particularly true in nonuniform deposits like Vermont talc occurrences. Geologic mapping and rock sampling should continue in both underground and open pit mines as new exposures are made through the mining process. This cumulative data set then guides the mining process, hopefully keeping it within the desired boundaries of ore as determined or defined for that particular deposit.

On a daily basis, the boundary between ore<sup>8</sup> and waste is often determined visually by the mining equipment operator, based on his experience with that particular ore type. It is a common practice in some mines for the geologist to spray paint lines or otherwise mark the boundaries between ore and non-ore. Although to the miner the rock may look the same on either side of that line, these marks guide him throughout his shift. J&J and Imerys employees testified that it was their practice to measure the appropriate boundary by using the width of the excavator or loader bucket to stay within the desired boundaries (Hopkins dep. 169:9-19 (8/16/18) (J&J); Downey dep. 244:14-248:6 (8/7/18) (Imerys). The establishment of this boundary is usually based on the projection of data from drill holes (drill core logs)<sup>9</sup> and exposures in other parts of the mine that may only reflect an approximate boundary between ore and waste rock. In some instances, this boundary is so critical that in open pit settings blast hole drill cuttings are analyzed in advance of mining. In short, it is almost impossible to operate a mine in commodities that occur in relatively small irregular deposits such as high-quality talc without periodically incorporating host rock, low grade ore, and/or otherwise undesirable ore, into the material being removed from the mine and processed.

<sup>&</sup>lt;sup>7</sup> In late 2009 a plan to transition from Chinese back to Italian talc began in response to price increases in Chinese ore but was never implemented and Chinese talc remained the sole feedstock for domestic J&J body powder products (IMERYS 249655).

<sup>&</sup>lt;sup>8</sup> An ore is a type of rock that contains minerals that can be extracted from the rock for sale.

<sup>&</sup>lt;sup>9</sup> Drill core logs were not made available from either Italy or China.

In Vermont, the talc deposits are structurally complex and irregular. <sup>10</sup> A 1992 memorandum by J.P. Grange describes the variability of the ore observed during a visit to the Vermont operations: "the ore bodies contain a variety of ores with very different qualities. The ore changes completely on very short distances. A highly selective mining method must be enforced in order to supply the right ore grade to each end product" (Imerys 145198). Because of the variability of the ore, it would be impossible to mine these talc ores underground without incorporating at least some host rock or lower grade ore, each potentially containing carcinogens such as asbestos and/or excessively high levels of certain heavy metals. Ore control in open pit operations benefits from adequate lighting but typically is impacted by less precise mining in the context of ore versus nonore due to increased equipment size, blasting characteristics, and weather. The unintended mixing of good ore with lower grades or host rock by blasting can be of particular concern, making blast hole spacing, depth, and charge size of critical importance, especially near ore body margins.

Imerys encountered difficulties when attempting to control ore quality at the Argonaut mine through selective mining<sup>11</sup> (IMERYS 132823): "it is very critical that care be exercised near the limits of the talc zones as serpentine and arsenic are commonly found there. In theory, the ore is segregated by talc content, color, and arsenic content at the mine face, but in actuality, mine ore control is rudimentary and is generally based on post milling rather than drill hole analysis." The need for careful selective mining relative to the control of potential fiber-bearing zones in Vermont was emphasized in a Cyprus interoffice correspondence (IMERYS 219720):

"tremolite in these deposits is encountered in the contact zones between the talc and the surrounding schist; in "grey talcs" in the vicinity of the contacts; and associated with the chlorite/amphibole waste zones within the talc ores that are locally termed "cinders". Cyprus maintains a selective mining program in Vermont that is directed toward exclusion of all these potentially fibre-bearing zones from the ores sent to the mills, and those suspect tonnages, including the associated talc, are left in the pit walls or sent to waste piles"

The 1989 agreement between Windsor Minerals and Cyprus Minerals stipulates that "the Hammondsville and Argonaut ore bodies are approved for carefully controlled and selective mining for ore for use in the preparation of Grade 66 talc" (IMERYS 235927 (Ex. E). This historical document makes clear that J&J and Imerys recognized the high variability of ore in its Vermont Mines. Complexity of the Argonaut ore body is further reflected in the fact that between 1972 and 2007 there were at least eight core drilling programs that produced 51,000 feet of core and an additional 340 air rotary holes that were sampled and "assayed" (IMERYS 238270). The accuracy and use of these drill-produced data sets were questioned in a 2008 Rio Tinto Minerals report (IMERYS 441340 at 361-365). Having reviewed the available photos of the relevant Vermont talc mines, it is not clear to what extent selective mining was utilized as it is not obvious

<sup>&</sup>lt;sup>10</sup> The structurally complex and irregular nature of the Vermont talc deposits has been shown in numerous reports: the detailed thesis work of Seymour on the Johnson mine (JNJ 000320138); the US Bureau of Mines (USBM) report on the same mine (JNJ 000306623; IMERYS 533358); Argonaut mine maps, core logs, and reports (IMERYS 418940, IMERYS 441340, IMERYS 501883 at 885, and IMERYS 501902); the comprehensive reports on the Hammondsville mine by the Colorado School of Mines Research Institute (CSMRI; JNJ 000245002); and by Gregg (IMERYS 436972).

<sup>&</sup>lt;sup>11</sup> The difficulty Imerys faced with controlling ore for quality and purity is indicated by the fact that air track (blast hole) drill cuttings were routinely analyzed (as in 1994 for example, IMERYS 048393).

in the photography of the Argonaut, Rainbow, and Hamm mines as shown below and in the photos which appear in Appendix B.



Downey Ex. 24, at p. 23 (Argonaut); photograph taken in 2002 or before.

Chinese talc was considered by J&J suppliers at least as early as 1983 when initial testing indicated that relatively high-quality talc was available there (JNJ 000059273). In 2003, J&J began to purchase Chinese talc from Imerys for its talcum powder products. The Chinese talc occurrences are exploited in government-owned mines by open pit methods (described in a 2011 site visit report by R. J. Lee Group (JNJ 000133309) and related presentation by J&J employee Mark Zappa (JNJ 000415546). As in most Chinese mines where a relatively high-quality product is required, and labor is cheap, in-pit hand sorting of broken ore from small blasts is common and this technique was used in the production of J&J talc. Such attempts at quality control are often based solely on talc color rather than mineralogical variations unless they are obvious. This is an imprecise method to ensure that unwanted components are removed from the talc ore.

Limited information about the actual mining of the Chinese talc is known. For example, a Rio Tinto response to the J&J Talc Suppliers Assessment Questionnaire states that Rio Tinto has a 20-year relationship with the state owned mine (IMERYS 036999;), but little is known about the drilling or other testing that was performed. (Downey dep. 349:1-352:17 (8/17/18) (Imerys). It is known that Rio Tinto identified problems with Guangxi talc ores in 1997 which resulted in the recommendation that a Luzenac representative be present at the mine during the mining and sorting process (IMERYS-A\_0015758). According to testimony of Imerys' corporate representative Patrick Downey in his 2018 deposition, this recommendation was not implemented (Downey dep. 371:12-20 (8/08/18). Neither core logs from the Chinese mine nor detailed maps of the drill hole locations or ore deposit geology were provided. (Downey dep. 349:1-352:17 (8/17/18) (Imerys). Moreover, maps of the actual mine as it has been exploited over the last fifteen years have not been provided. *Id*.

# a. Beneficiation process<sup>12</sup>

Many talc ores contain in the range of 50%-70 % talc, yet specifications dictated that the finished products have a talc content of 95% to 99%. To reach these high finished product percentages, non-talc material must be removed post mining. Additionally, this talc must meet specific physical, chemical, and mineralogical criteria. These beneficiation techniques can begin with visual examination and hand removal of unwanted materials from ore stockpiles. Formal processing is complex. (Roe, 1975). Steps include primary (jaw) crushing, grinding circuits including roller mills, shear disc devices, flotation, thickening, filtering, and drying. Early mill flow sheets illustrating processing of J&J talc are shown in IMERYS 469483 and IMERYS 054579.

Both J&J and Imerys used a flotation beneficiation process for Vermont talc. During this process, talc is typically floated away from magnesite and can be upgraded by classification and delamination processes, the result being very tiny grains that are also very thin. Flotation agents used or considered for adoption included Ultrawet D. S. and a blend of n-butanol and citric acid. Certain iron-bearing minerals may be removed by magnetic separation. Silicates such as chlorite and amphibole family minerals can report with talc and be incorporated in the finished product. Nonmagnetic heavy minerals such as some sulfides and arsenides may report with the non-talc sink fraction during flotation and be discarded with tailings. In some instances, these minerals may be removed by shaker tables. In recent years photo sensitive devices, shape sorting, and friction sorting have been available for use early in the processing flow path.

A review of milling and beneficiation practices employed in Imerys's Houston plant indicates that the flotation method utilized for decades in Vermont, was not used but rather a series of grinding and air classification processes (IMERYS 132770; IMERYS 416471).

Quality control issues are discussed further below under "SAMPLING AND TESTING." Regardless of the beneficiation process that was employed, contemporaneous testing of processed talc makes it clear that non-talc material such as asbestos and high concentrations of some heavy metals were included in finished products.

### **B.** MINERALOGY

The mineralogy of the deposits from which Johnson & Johnson's talcum powder products were sourced include the asbestos species chrysotile, tremolite, actinolite, and anthophyllite. In addition, the deposits contain fibrous talc, an asbestiform mineral that has been determined to have similar harmful effects as asbestos (IARC, 2010, 2012).

<sup>&</sup>lt;sup>12</sup> Beneficiation is any process that improves the economic value of the ore by removing the gangue minerals which results in a higher-grade product and a waste stream (tailings).

# i. Italy

Deposits derived from sedimentary carbonate rock, such as the Italian deposits, typically contain accessory minerals that may include asbestos (actinolite and tremolite in asbestiform habits) and the chlorite family minerals. Mineralogical work on Italian talc was conducted in the 1970's by University College in Cardiff, Wales. This research identified the presence of both tremolite and actinolite in associated rocks. These minerals were fibrous in some cases (JNJ 00030983; JNJ000016791; JNJ 000060592; JNJ 000238194; and JNJ 000322351). Tremolite is described in Italian talc in a 1973 report (JNJ 000270588). Battelle Memorial Institute analyses dated 5/9/58 indicate 1% tremolite and fibrous talc from between 8% and 10% in Italian ores (Ex. 24, Hopkins deposition). Both fibrous anthophyllite and fibrous talc were identified by Cyprus Industrial Minerals in 1984 in its Italian talc (Ex. J&J 177, Hopkins deposition). Work done for Johnson and Johnson in 1971 by the CSMRI indicate the presence of both talc and nontalc needles in Italian talc product (Ex. J&J 256, Hopkins deposition). Chrysotile is also reported in the Val Chisone mineral suite in 1971 by Ashton (JNJAZ55-000006103). A summary talc report by Rio Tinto Minerals points out that accessory minerals in Val Chisone talc deposits include actinolite-tremolite, anthophyllite, serpentine family minerals, and quartz (Ex. 8, Downey deposition). Fibrous tremolite was reported from Italian tale as late as 2009 (IMERYS 445999). Mineralogical compilations shown in Mindat.org indicate the presence of actinolite and tremolite in a number of the Val Chisone district ores. A paper describing asbestos in Italian talc deposits was published by Marconi and Verdel in 1990) For a more complete recitation of test results finding asbestos in Italian talc, see subsection iv. below.

#### ii. Vermont

Vermont talc deposits are derived from alteration of serpentinites and are known to locally contain asbestos (chrysotile and amphibole species in fibrous asbestiform habits). Mineralogically, the Vermont and similar talc ores consist of talc, carbonate minerals (often magnesite), and one or more of a variety of accessories that can include members of the chlorite family, clays such as kaolinite, sulfides, arsenides, amphiboles, serpentine family minerals, quartz, phlogopite, and albite. A summary report by E. F. McCarthy of Luzenac dated February 2010 (IMERYS 081025) indicates that Vermont talc ore mineralogy includes one to five percent serpentine minerals<sup>13</sup> and chlorite.

In 1972, asbestos was declared a carcinogen by the WHO's International Agency for Research on Cancer (IARC 1973, 1977, 1987a, 2012). Several talc-associated minerals were designated asbestos at this time, making their incorporation in most finished products unacceptable. Initially the list of asbestos minerals was short, consisting of a single serpentine mineral (chrysotile) and fibrous varieties of five amphiboles (tremolite, actinolite, anthophyllite, cummingtonite-amosite, and riebeckite-crocidolite). Actinolite and anthophyllite are root names for various species rather than distinct minerals, as they were once considered.

<sup>&</sup>lt;sup>13</sup> Chrysotile is an asbestiform serpentine mineral.

Based on the mineralogy of Vermont talc deposits, the potential for asbestos to be present in J&J's talcum powder products was significant. <sup>14</sup> Potentially asbestiform amphiboles such as actinolite, tremolite, anthophyllite, and cummingtonite are reported from a variety of Vermont talc-related serpentinite localities. These include the Carlton talc mine in Chester, Windsor County and other Vermont serpentinite- related actinolite or tremolite occurrences as documented by Seymour (J&J 0053200) at Hammondsville, the Barton steatite quarry, Holden talc quarry, Rochester verde antique quarry, and the Mad River mine.

A literature review for Vermont talc- associated asbestos occurrences results in a Jahns (1969) report of chrysotile from Roxbury. King and Cares (1996) report actinolite and/or tremolite occurrences in the Belvidere talc mine in Lamoille County, the Mad River talc mine in Washington County, the Duxbury serpentine quarry and Waterbury talc mine in Washington County, the Newfound soapstone mine in Windham County, the Bethel talc mine and Davis soapstone quarry in Windsor County, and the Williams talc mines in Rochester, Windsor County. "Asbestos" is described by King and Cares (1996) from the Johnson talc mine in Lamoille County and the Williams talc mine at Rochester, Windsor County. The United States Geological Survey (USGS) Mineral Resources on-line spatial data site reports "asbestos" from the Rochester or Williams talc mine in Windsor County indicating that it is a deposit related to serpentinites. Asbestos is similarly reported for the Greeley talc mine in Windsor County. The talc deposits described in these publications occur as a part of the same geological belt as the mines that sourced J&J's talcum powder products

Serpentine asbestos (chrysotile) and amphibole asbestos has been found in Vermont talc used to source J&J talcum powder products. Chrysotile within talc utilized by Windsor Minerals was known at least as early as 1974 as indicated in the Zeitz memorandum of 5/14/74 (IMERYS 209320) where chrysotile suppression by experimental flotation agents is discussed. In 1991, Dr. Alice Blount reported the presence of asbestos needles and fibers in Vermont talc which she later confirmed to be J&J baby powder (Blount (1991); Ex. J&J 220, Hopkins deposition; Dep. Alice Blount, PhD. (4-13-18)). Results of other tests conducted by J&J and Imerys are consistent with reports of asbestos in the published literature. A table containing results of asbestos testing performed or commissioned by J&J and Imerys appears at subsection "iv. Some testing…" below.

In addition to the published literature, a 1991 report under the sub-heading "Fibrous Minerals" states that tremolite and actinolite are considered relative to several zones in Vermont mines with potential problems related to fibers in both dump rock and product. (IMERYS 425354) An internal study performed by Imerys's predecessor Cyprus Minerals in 1992 points out that mines in the Ludlow area (Rainbow, Black Bear, and Argonaut) contain high fiber areas that must be excluded (IMERYS 425354 at 385). Amphibole in amounts less than 0.1% were found in float feed and Hamm mine ore as reported in a product certification report in 1992. (IMERYS 151337 at 370-371). Finally, undated hand-written notes contained in Imerys data (IMERYS-MDL-AB\_0005560 at 585) report about 25% actinolite in Hamm mine transitional country rock, up to 88% actinolite in chlorite schist from the Hamm open pit, and approximately 16% actinolite in Hamm mine open pit talc from near the hanging wall of the ore body.

<sup>&</sup>lt;sup>14</sup> This is further supported by the fact that commercial asbestos has been produced in large quantities from Vermont serpentinite-related deposits.

Concern with incorporating serpentine and lamprophyre from dikes into processed Vermont ore was expressed in 2006, suggesting a maximum of 2% for serpentine. (IMERYS-A\_0015174) The document states that these two rock types, both of which can have associated amphiboles, have always been present in varying amounts from the ppm range to whole percentages of the extracted ore.

Testing of talc prior to shipment is, however, generally described in IMERYS 036999 at 7003 and IMERYS 041522 at 526. Screening talc ore samples for trace to small amounts of specific amphibole species by X-ray diffraction (XRD) is inadequate because of its high detection limit

Other minerals consistently reported in Vermont talc ores include the carbonates dolomite and magnesite; magnetite, chromite, and other unspecified opaques and chlorite family species. Some opaques could be unspecified arsenic, cobalt, nickel, or chromium minerals. Chlorite family species can contain significant heavy metals such as chromium and are consistently reported in core logs as in the Argonaut mine (IMERYS 469483 at 484 for example) and an average chlorite content of 4.01% is reported for its ores in a reserve study produced in 2008 (IMERYS 441340 at 364). Serpentinites are typically deficient in free or crystalline silica (quartz). However, quartz veins are reported for some Vermont talc mines, such as the Hamm mine. (IMERYS 238270).

# iii. China

Less is known about Chinese talc deposits. Drill core logs, drill core testing data, on-site mine testing data, mine planning documents and data, and mine maps have not been provided. However, from what has been made available, accessory minerals associated with Chinese talc utilized by J&J include minor carbonates and chlorite family minerals to as much as 17.3%. (IMERYS-A\_0015758 at 760) Early analyses of Guangxi #2 and #2A talc (1998) indicate chlorite contents exceeding 9% (IMERYS 403794 at 804). Upper limits for chlorite in Guangxi #1 was specified as 2% (IMERYS 403794 at 803) while the upper chlorite limit for Guangxi #2 was not given.

In 2010, Imerys employee Ed McCarthy<sup>16</sup> reported the presence of tremolite in Chinese talc ores (IMERYS 081025). In a subsequent presentation (2014), Mr. McCarthy indicates Chinese talc ores in use by Imerys contain up to 15% chlorite, 10% carbonate minerals, and 1% quartz (Ex. 47, Downey deposition). Asbestos testing was reportedly conducted in China, uniformly negative results being shown on periodic certificates of analyses. Initial site qualification sampling and testing ostensibly was conducted or otherwise approved by Rio Tinto (though to the extent reports or materials exist, they have not been made available). There was a report of asbestos in Chinese talc in the late 2009 (IMERYS 309326). In 2016, chrysotile particles were found in talc mined in China (JNJ 000521616).

In addition to the instances below in subsection "iv" where Defendants' own testing was positive for the presences of asbestos, Dr. William Longo has tested historical samples from

<sup>&</sup>lt;sup>15</sup> I understand that this material has been requested, but it not made available.

<sup>&</sup>lt;sup>16</sup> Ed McCarthy was Technical Director for Imerys Talc America, Inc.

Defendants. He reports positive test results for asbestos in talc originating from Italy, Vermont and China.

# iv. Some Testing Performed by or for Johnson & Johnson & Imerys Are Positive for Asbestos

Results of tests conducted by or for J&J and Imerys are consistent with reports of asbestos in the published literature. I have reviewed the January 15, 2019 report of Dr. William Longo and Dr. Mark Rigler reporting test results on numerous talcum powder product samples produced in litigation and demonstrating that approximately 67% of the samples were positive for amphibole asbestos. Specifically, 19 of 28 historical Johnson's Baby Powder samples were positive or 68%; 17of 22 historical Shower to Shower samples were positive or 77%; and 8 of the 15 individual Imerys railcar samples were positive or 53%.

The testing results appearing in the Table<sup>17</sup> below are some of the reported instances within Defendants' internal documents where serpentine asbestos (chrysotile), amphibole asbestos, or potentially asbestiform amphiboles have been found in samples of talc used to source J&J talcum powder products:

Date	Exhibit #/Bates No.	Testing Entity	Mine	What was tested	What tests revealed
10/15/1957	J&J-309	Battelle		Italian talc	"the Italian tale averages about 10% fibrous or acicular particles"
1/24/1958	J&J-310	Battelle		Italian talc	3 to 10% non-platy with trace amounts of tremolite
5/9/1958	J&J-1	Battelle	Val Chisone	processed talc Italian 1	tremolite
5/9/1958	J&J-311	Battelle		Italian talc	"acicular and fibrous particles of tale"; the 8 to 10% of non-platy tale is presumed to be derived from tremolite or enstatite"
5/23/1958	J&J-2	D-44-11-	Val Chisone	processed talc-	tremolite;
5/23/1958	J&J-2	Battelle	Vai Chisone	Italian 1	6 to 10 % fibrous tale
9/18/1961	J&J-313	Battelle		Hammondsville core	2 percent non platy talc in upper core; 14% (granular and fibrous) non platy talc with 1-2% altered amphiboles in lower core
12/4/1970	J&J-9	Colorado School of Mines	Hammondsville	38 core samples	tremolite-actinolite; fibrous tale

<sup>&</sup>lt;sup>17</sup> The Table is largely composed of the chart produced during the deposition of Johnson & Johnson corporate representative Dr. John Hopkins and which was marked as Exhibit 28. (Hopkins dep, 1243:12-1244:19 (11/5/18).

Date	Exhibit #/Bates No.	Testing Entity	Mine	What was tested	What tests revealed
3/9/1971	J&J-257	McCrone		Shower to Shower; medicated powder	"fiber of chrysotile. Was very clear";   "medicated powder we found one   fiber of chrysotile"; Shower to   Showerwe feel strongly that it may   be chrysotilechrysotile is very low";   >>> Final Report >>> "Shower to   Shower The fiber content of Shower   to Shower is quite low in comparison   to previous samples which we have   investigatedWe found three suspect   fibers. Of these, two were found in   one field and probably have the same
5/14/1971	J&J-255	J&J		Baby Powder (production batch)	tremolite; tremolite-actinolite
7/2/1971	J&J-256	Colorado School of Mines		six monthly plant run samples	5 of 6 show tremolite-actinolite; "no other forms of non-tale minerals approaching asbestos types were identified"
7/7/1971	J&J-15	Colorado School of Mines	Vermont talc	processed talc-344- L	tremolite & actinolite
7/29/1971	J&J-19	Colorado School of Mines, McCrone, Dartmouth	Vermont talc		"trace amounts of fibrous minerals; (tremolite/actinolite) "
10/12/1971	J&J-23	McCrone		Shower to Shower	traces of chrysotile in one of additives
8/3/1972	J&J-28	NYU		Shower to Shower sample 84	5% chrysotile;
8/9/1972	J&J-342	J&J		Shower to Shower	"trace tremolite" in 1970 and 1971 samples
8/10/1972	J&J-373	J&J		Shower to Shower	"About 1 fiber or rod/needle every 500 particles. Approx. 1/3 of these are tremolite
8/24/1972	J&J-29	Sperry Rand		Shower to Shower	"asbestos fibers could be detected in the sample"; "reported chrysotile"
8/31/1972	J&J-348	Sperry Rand		Shower to Shower	Dr. Weissler used SEM "to study general shape of chrysotile asbestos." "Dr. Weissler he did find fibers which had the general shape of chrysotile". Also found "asbestos form fibers" In samples brought by JJ which were photographed."

Date	Exhibit #/Bates No.	Testing Entity	Mine	What was tested	What tests revealed
9/8/1972	D-7	Sperry Rand		Shower to Shower	Observation of asbestiform "more correctly be called fiber form". SEM "very able to identify fiber forms which may be chrysotile"
				J&J Medicated	Medicated Powder: tremolite 4%
9/26/1972	J&J-31	Dr. Lewin		Powder; Johnson's Baby Powder; J&J	Baby Powder: 2-3% chrysotile
				Shower to Shower	Shower to Shower: 2-5% chrysotile
10/27/1972	J&J-36,34,37	McCrone		Johnson's Baby Powder batch # 108T &109T	"Both samples contained an insignificant amount of tremolite;"
				(Lewin Samples)	tremolite rods
10/27/1972	J&J-263	J&J		Johnson's Baby Powder batch # 108T &109T (Lewin Samples)	"There are trace quantities [tremolite] present confirmed both by McCrone & Bill Ashton. Levels are extremely law but occasionally can be seen optically. This is not new."
??/??/1972	J&J-33	University of Minnesota		Shower to Shower	"chrysotile asbestos does exist in the specimens of shower to shower"
2/26/1973	J&J-100	Colorado School of Mines		processed talc	tremolite-actinolite; slight trace of anthophyllite? Chrysotile? "asbestos type materials"
4/19/1973	J&J-296	J&J		Johnson's Baby Powder	"four of the samples are suspected of containing tremolite based on the finding of one or two "fibers" per sample which satisfy the color/morphology criteria."
4/26/1973	J&J-44	J&J	Hammondsv ille	Johnson's Baby Powder	"tremolite or actinolite are identifiable (optical microscope) and these might be classified as asbestos fiber"
4/27/1973	J&J-335	J&J		Johnson's Baby Powder	"trace amounts of amphibole" in all 4 samples tested; "Shape- prismatic, columnar, parallel – sided rods"; Size: from 20X4 microns to 200X30 microns.; Identify: the optical properties of the particles are closer to actinolite than tremolite"
5/1/1973	J&J-367		Hammondsv ille	ore	"the ore body contains tremolite"

Date	Exhibit #/Bates No.	Testing Entity	Mine	What was tested	What tests revealed
5/8/1973	J&J-368	J&J	Hammondsv ille	ore	"Your question this morning was how did Lewin assay timing relate to actinolite showings. Baby Powder lots 108T & 109T were alleged to contain asbestiforms by Lewin. Talc shipments checked by microscope hare showed all lots clean just prior to and right after that time. the first showing of actinolite we know about is October 1972. The indications are that things were in good shape when Lewin picked up the above two lots for his assays."
6/6/1973	J&J-47	Cardiff	Vermont	talc samples	actinolite
8/27/1973	J&J-299	Dutch consumer organization		Johnson's Baby Powder	" asbestos – content of 1.59%"
9/6/1973	J&J-258	FDA		Shower to Shower sample 84	"fibers of tremolite/actinolite"
12/21/1973	J&J-263	Colorado School of Mines	Vermont	talc samples	"identified chrysotile at a level of less than 10 ppm in the Vermont sample"
1/29/1974	J&J-57	McCrone; Dartmouth	Hammondsv ille	ore & product	"chrysotile fiber suppression was indicated";  Dartmouth finds amphibole 100 to 200 ppm in ore and 3000 in ore;  McCrone finds chrysotile in ore and finished product
3/1/1974	J&J-58	Dartmouth	tale product & ore from Windsor	ore & product	"ore sample contains 2300ppm actinolite and the talc product contains 170 ppm actinolite"; "small amounts of anthophyllite may be present"
4/24/1974	J&J-65	McCrone	Argonaut	ore	TEM finds chrysotile and fibrous tremolite
5/8/1974	J&J-66	McCrone		Windsor 66 ore & product	ore-fiber probably tremolite & chrysotile; product- one chrysotile fiber
5/9/1974	J&J-366	McCrone	Argonaut	ore & product	chrysotile fibers in ore and product of 1/3 of samples tested

Date	Exhibit #/Bates No.	Testing Entity	Mine	What was tested	What tests revealed
5/14/1974	J&J-370	McCrone; Dartmouth	Hammondsv ille	Windsor 66 ore & product	Table 15 McCrone Summary- probable chrysotile in 2 samples and chrysotile in 2 other samples. >>>Attachment A Dated 05-08- 74>>>>> "Sample 66-AC ore showed chrysotile fibers but in the product from the same ore benefaction had reduced the chrysotile content to 1 fibril as mentioned above. The chrysotile fiber content of Sample 66-AC-ore represents an estimated chrysotile content of<1-2 ppm, thus, even in the worst case, the level of asbestos contamination present in these ores is minimal.">>>>>>>Attachme nt B>>>>>>> "fibrous form of anthophyllite which occurs as a rare mineral in the Hammondsville ore body."
10/10/1974	J&J-74	McCrone		product	"fibrous asbestiform material" "chrysotile fibers were found"
10/19/1974	J&J-75	Cyprus		talc samples	the "presence of asbestos mineral in both samples": "tremolite was readily apparentpossible chrysotile was also observed"; "the presence of tremolite form of asbestos"
7/1/1975	J&J-89	McCrone		"from your ore body"	"confirmed asbestos" low to medium; "bundles of amphiboles"
9/9/1975	J&J-92	Mt. Sinai		Johnson's Baby Powder	anthophyllite & tremolite
9/11/1975	J&J-297	McCrone		A-HC	chrysotile fiber
11/5/1975	J&J-97	McCrone		ore	Table 1 lists "fibers of asbestos"
1975	IMERYS 210810	McCrone		Windsor Minerals samples	chrysotile
7/5/1976	J&J- 303	Colorado School of Mines		Johnson's Baby Powder	"small (1%?) amounts of amphibole needles."
1/25/1977	J&J-141	Cardiff		Vermont composite sample	fibers of antigorite
6/14/1977	J&J -246	EMV		ore & product	composite samples-large and small fibrous tremolite
10/4/1977	IMERYS 210707	McCrone		40 talc samples	chrysotile in CI-J

Date	Exhibit #/Bates No.	Testing Entity	Mine	What was tested	What tests revealed
10/5/1978	IMERYS 210707	McCrone		38 talc samples	chrysotile fiber in 2 samples
2/9/1979	J&J-164	George Lee's Group		66 composite samples	tremolite & actinolite
2/9/1979	J&J-341	J&J		Windsor 66 composite sample	"massive amphiboles in the 66 composite sample of Nov 6-10. the sample was forwarded to George Lee's group where the present of amphiboles was confirmed. They were identified as tremolite & actinolite"
9/8/1980	IMERYS 210707	McCrone		#TC-V	one fiber of chrysotile
11/6/1980	J&J-169	McCrone		"talc sample"	chrysotile asbestos
9/1/1983	J&J-175	McCrone	Argonaut; Rainbow	air samples	Argonaut - 118 fibers; Rainbow- 2650 fibers
1/12/1984	J&J-305	McCrone		Talc powder, grade EV	" sample contains2 to 3% by weight tremolite-actinolite. The tremolite-actinolite in the sample is considered to be asbestos by current government regulations; however, it appeared to be cleavage fragments of the massive form rather than true asbestiform. typical tremolite fibers from the sample are shown."
11/2/1984	J&J-179	McCrone		air samples	6,600 to 60,000 chrysotile asbestos fibers. All samples found asbestos
5/15/1985	J&J-177	MSHA	Italian talc	air samples at Cyprus South Plainfield	71.2% fibrous tale & "5.8% anthophyllite, an asbestiform amphibole"
8/22/1985	JNJMX68_0 00013019	McCrone	McCrone Project No. ME-1862	Sample (WMI 85-28 & WMI 85-30)	Chrysotile asbestos
4/29/1986	J&J-182	McCrone		talc samples	chrysotile detected in all samples
8/5/1986	J&J-184	McCrone	Hammondsv ille	air samples	fibers in both samples
3/30/1987	J&J-185	J&J	Raymond Mill	Processed talc	"Tremolite is present in the fines (minus 100 plus 200 mesh) in six volume percent as free needles"
3/14/1988	JNJ0000621	RJ Lee	J&J talc	Sample	.0024% chrysotile;
3/17/1900	76	To Lee	sample	(879-57 Talc L)	.014% fibrous tremolite
4/15/1988	J&J-190	Skyline Laboratories; Aquatec Environmental	Chester/Ha mm	random and composite process samples	actinolite
1988	J&J 0144301 (Julie Pier Ex. 34)			Vermont	fibrous tremolite at 0.14%

Date	Exhibit #/Bates No.	Testing Entity	Mine	What was tested	What tests revealed
5/23/1989	JNJNL61_00 0006792	RJ Lee	talcum powder	Sample (736-116)	2 chrysotile fibers
7/31/1989	JNJ0002234 49	RJ Lee	J&J talc sample	Sample (731-120)	3 chrysotile fibers
11/19/1990	J&J- 0007797		McCrone Cyprus Windsor Project	Sample (CWM 90-28)	1 chrysotile fiber
11/20/1990	J&J- 0007801		McCrone Cyprus Windsor Project	Sample (CWM 90-29)	Serpentine (Antigorite)
	JOJO-		McCrone	Sample	
12/5/1990	MA90013- 0005		J&J talc sample	(33-HV66)	One serpentine (antigorite?) fiber
1990	J&J 0007797			West Windsor sample (CWM 90-28)	Anthophyllite
1990	IMERYS 238478 IMERYS 238468 IMERYS 238457		Cyprus Windsor	Sample	Actinolite and tremolite in float feed and conditioner slurry
1/10/1991	IMERYS211 157	Dr. Blount	Blount Study	Baby Powder made from Vermont talc (Sample 1)	Tremolite needles and fibers
1991	J&J-327	Cyprus	Argonaut mine		"Argonaut main ore body open pithigh incidence of fibre bearing zones encountered in the main ore body"
2/25/1992	J&J-202	Cyprus	Argonaut; Hammondsv ille; Black Bear	ore	"fibrous tremolite was identifiedin exposures and cores at the east Argonaut 7 Black Bear mines. Cyprus staff report past tremolite from the Hammondsville and Clifton deposits."
3/25/1992	IMERYS219 720		Cyprus Ore reserves: arsenic and tremolite	Ore	Fibrous tremolite
7/2/1992	IMERYS051 370		Luzenac found amphibole in West Windsor	Float feed (CWM 92-12; 92-16)	<1% amphibole (actinolite and actinolite cleavage fragments)
1993	IMERYS 238270		Hamm	ore	Fibrous actinolite

Date	Exhibit #/Bates No.	Testing Entity	Mine	What was tested	What tests revealed
7/15/1994	IMERYS 051442	Luzenac	West Windsor float feed and slurry	Float Feed	<.1% tremolite
11/3/1994	IMERYS 051436	Luzenac	West Windsor slurry	Slurry	<.1% amphibole (actinolite in the form of cleavage fragments)
2/8/1995	IMERYS 442232	Luzenac	McCarthy found needles from Argonaut Ore	Ore	Needles
10/13/1995	JNJ0000639 51	RJ Lee	talcum powder	Product (Sample A-1)	tremolite particle in Sample A-1
3/26/1996	JNJMX68_0 00004296		J&J V-96 talc	Tale product	Amphibole
8/25/1998	IMERYS 548407	Bain Environmental		Talc Samples	Sample LAI 98-04 was found to contain two fibers that are suspect amphibole minerals, having an aspect ratio greater than 10:1.
12/13/2000	IMERYS 548366	Bain Environmental		Float Feed	Trace amount of chrysotile fibers in first sample.
4/2/2001	IMERYS189 001	Luzenac	Argonaut Ore to West Windsor Mill	Ore	1 chrysotile fiber
1/1/2002	IMERYS 130504	Imerys	Grade 96	Ore	Chrysotile (1 structure ≤ 5 μm)
6/1/2002	IMERYS 130504	Imerys	Float Feed	Ore	Chrysotile (1 structure ≤ 5 μm)
9/1/2002	IMERYS 130504	Imerys	Float Feed	Ore	Chrysotile (1 structure ≤ 5 μm)
10/1/2002	IMERYS 130504	Imerys	Grade 96	Ore	Chrysotile (1 structure ≤ 5 µm)
2001-2002	IMERYS 499486	Imerys	Drilling program	Drill core samples	Fibrous tremolite
2003	IMERYS 499264	Imerys	Drilling program	Drill core samples	tremolite to 4% in 1998 Argonaut drill core
2/24/2004	JNJ0003753 83	Forensic Analytical	TEM Analysis on behalf of KRCA in Sacramento, CA by Forensic Analytical	Baby Powder made in Vermont	0.2% Anthophyllite Asbestos

Date	Exhibit #/Bates No.	Testing Entity	Mine	What was tested	What tests revealed
2005	IMERYS 533753		Argonaut	Ore	Talc and actinolite needles detected.
	IMERYS				Tremolite fibers found in serpentinite bodies within the deposit.  Drill hole R98-02 indicates fibers
9/29/2006	533694		Argonaut	Ore	in the core. Confirmed in samples sent to Denver.

### v. Fibrous Talc

Although a relatively simple mineral, talc owes a significant degree of its commercial importance to morphological and physical properties such as its common thin foliated habit and softness. In some instances, however, the morphology of individual talc particles is not the desired thin plates but is represented by a fibrous or asbestiform habit. When talc occurs in this form, it is considered fibrous in nature, taking an asbestiform habit. IARC has concluded that talc with asbestiform fibers should be considered a carcinogen similarly to asbestos (IARC 2010, 2012).

There are numerous reports of the presence of fibrous talc in J&J and Imerys's talcum powder products. The chart below contains a summary of some of the documents describing the presence of fibrous talc. Detailed study in the 1970's and later identified spindle, rolled, and fiberlike talc in samples analyzed by commercial labs and others (IMERYS 210707 at 802 for example). Petrographic examination of Hammondsville samples in 1970 identified fibrous talc in many thin sections in amounts up to 20% (JNJ 000245002 at 040) for example. Early research by CSMRI for J&J identified by point count analysis 3.6% "free talc needles" in a submitted sample (No Bates No., report dated 11/05/1971, CSM project #10704).<sup>18</sup> Even earlier work by CSMRI also identified fibrous talc as in letters by Reid dated June 3 and June 23, 1970 (no Bates numbers). Other CSMRI reports to J&J in 1971 consistently identified fibrous talc in various sample reports (CSMRI project # 390517). Talc samples submitted to McCrone from Windsor Minerals between 1974 and 1977 also reported fibrous talc in various samples (IMERYS 210707 at 811, 815, 831, 847, and 853). Fibrous talc or "talc needles" were identified in a J&J sample in 1978 (IMERYS 210707 at 801). As recently as 2009, fibrous talc was still being found in talc used in J&J talcum powder products as discussed in an R. J. Lee Group memorandum to J&J (JNJ 000092227). Other testing results where fibrous talc has been documented are listed in the following Table:

Bates Number	Date	Location Found (Mine/Ore/Product)	Finding
JNJ000085374 JNJNL61_000000266	March 1945 Sept. 1945	Domestic/ Probably Vermont talc	Very coarse, fibrous talc Granular and Scaly - Aggregates of fibrous to scaly talc are apparent

<sup>&</sup>lt;sup>18</sup> Even earlier work by CSMRI also identified fibrous talc as in letters by Reid, dated June 3 and June 23, 1970 (000526).

Bates Number	Date	Location Found (Mine/Ore/Product)	Finding
JNJNL61_000001341	5/23/1958	Italian ore and Italian floated ore	Italian No.1 and Italian No.2 (6% fibrous; 8-10% fibrous) (p 1350); Raw Italian No.1 (9% fibrous) (p 1360), Raw Italian No.2 (5% fibrous) (p 1360), Floated Italian No. 2 (3% fibrous) (p 1359)
JNJS71R_000001978	12/4/1970	Hammondsville Mine	Drill hole 1-67H: 10-20% fibrous talc (p 2016);  Drill hole 6-67-H: 5-20% fibrous talc (p2017);  Drill hole 21-67-H: <1% fibrous talc (p2018);  Drill hole 35-67-H: 10-20% fibrous talc (p2019);  Drill hole 36-67-H: 2-10% fibrous talc (p2020);  Drill hole 38-67-H: 5-20% fibrous talc (p2022);  Drill hole 39 thru 41-67-H: 5-12% fibrous talc (p2023-5);  Drill holes 44 thru 45-67-H: 2-5% fibrous talc (p2026-7);  Drill hole 46-68-H: 3% fibrous talc (p2028);  Drill hole 49-68-H: 1% fibrous talc (p2029);  Drill hole 50-68-H: 3% fibrous talc (p 2030);  Drill hole 55-68-H: 5-10% fibrous talc (p2031)
JNJ 000234805	6/24/1971	Grantham, Italian & Vermont Talc Final Products	Talc Needles: 2.2%; 1.4%; 0.8%; 1.2%; 0.8%; 1.4%; 0.6%; 1.0%; 1.8%; 2.2% (p 4810); Talc Shards: 2.8%; 4.8%; 5.2%; 3.0%; 2.8%; 2.2%; 1.4%; 1.6%; 3.8%; 1.6% (p 4810); Talc Needles: 0.020%; 0.026%; 0.012%; 0.084%; 0.011%; 0.022%; 0.004%; 0.05%; 0.0295%; 0.03% (p 4812); Talc Shards: 0.41%; 0.617%; 0.944%; 0.42%; 0.404%; 0.283%; 0.792%; 0.15%; 0.7311%; 0.45% (p 4812)
JOJO-MA2330-0001	8/19/1971	J&J Baby Powder	12 fibers seen in sample from batch 344L, all but one were identified as rolled or folded talc particles, the remaining wasn't positively identified, but it was suggested not asbestos (p 0034).

Bates Number	Date	Location Found (Mine/Ore/Product)	Finding
JNJNL61_000024657 (letter); JNJNL61_000024650; JNJNL61_000032036	10/12/1971	Italian ore; Medicated Powder; Shower to Shower	Italian: Domestic ground Italian sample showed more fibrous talc than the Italian ground; Medicated powder: few examples of fibrous talc; S2S: talc patterns which appear as fibers
JNJNL61_000033574	10/22/1971	"Sample 228-P"	3.6% "free talc needles"
JNJNL61_000023234 JNJ 000229914	10/27/1971	J&J Baby Powder Product	A few fibrous talc particles
JNJNL61_000024449	11/10/1971	"J & J baby talc" - Dr. Langer	"many fibrous talcs"; chrysotile
JNJ000238826, JNJ000248023	5/25/1972	FD-14 Tremolite Talc examined by McCrone	50% Fibrous Tremolite, 10% Antigorite, 35% talc of which about 75% is platy and 25% is rolled or fibrous, 2-5% Chlorite under one testing method, under another it was more like 60% Amphibole Tremolite, 15-20% platy talc, 20- 30% fibrous talc and talc shards and 1% Carbonate mineral Looking at X-Ray Diffraction of FD-14 found 10% additional fibrous talc
JNJ000314680	6/27/1972	NIOSH testing of 7 talcum powders	7 samples previously analyzed and diagnosed as having varying amounts of fibrous tale, J&J Medicated powder and Johnson's Baby Powder were both tested to see how many fibers a mother/baby would be exposed to.  Medicated powder: mother: 06 fibers/field; baby: .05 fibers/field  JBP Mother: .08 fibers/field  Desitin - Mother: .17 fibers/field  paby: .09 fibers/field

Bates Number	Date	Location Found (Mine/Ore/Product)	Finding
JNJNL61_000025152	9/8/1972	Italian mine	Specimen I8: fibrous aggregates in the finer talc lenses (p 5166); Specimen I22: fibrous clusters of talc (p 5183); Specimen I24: fibrous aggregates within the main mass of talc (p 5183); Specimen I26: fibrous and feather aggregate of talc (p 5187); Specimen I45: talc ore containing randomly oriented 'matted' aggregate of fibrous talc (p 5200)
JNJS71R_000009825	4/26/1973	J&J Baby Powder	"Our Baby Powder contains talc fragments classifiable as fiber." "no final product will ever be made which will be totally free from respirable particles."
JNJS71R_000007083	9/19/1973	Vermont talc	Dr. Pooley reports Vermont talc contains about 1% fibrous talc
JNJS71R_000000139 JNJ000086280	9/28/1973	J&J Baby Powder Product; Italian Cosmetic Talc - Val Chisone	Fibrous talc particles in J&J BP and Val Chisone cosmetic talc. Dr. Pooley and Rolle discuss how fibrous talc may be misidentified as chrysotile
JNJ000232897	5/6/1974	JNJ Samples and a Merck sample	JNJ sample 00C6-406 was mostly platy talc with some fibrous talc which morphologically looks like amphibole
JNJS71R_000002199 JNJ000246844	5/8/1974	W. Windsor ore and talc products	66-A-ore: fibrous or rod-shaped particles appear to be talc; 66-U-ore: fibrous forms that are talc rolls and shards; 66-U-product: talc ribbons and rolled talcvery few inorganic fibers. One fiber resembled chrysotile; 66-AC-ore: fibrous content consisted entirely of talc rolls and shards; 66-AC-product: fibrous talc content, rolled talc and talc fibrils, one chrysotile fiber

Bates Number	Date	Location Found (Mine/Ore/Product)	Finding
JNJ000346572	7/17/1974	Johnson's Baby Powder Product	2 samples examined M & P - both samples found indications of carbon particles, Sample M also showed lots of talc fibers and rolled talc.  Sample P showed 1 particle of Chrysotile, Rolled and fibrous talc in sample M noted again
JNJ000222851	8/8/1974	Windsor minerals samples used primarily in roofing	One sample showed large blocky and fibrous talc particles, also showed small fiber of chrysotile
JNJ 000252742	8/8/1974	Windsor Minerals had McCrone test 6 samples of talc	Several samples showed chrysotile, sample C-GI 7-8-74 to 7-12-74 contains a relatively large amount of fibrous material
JNJS71R_000011316	10/10/1974	Windsor 11 samples	One sample found to contain fibrous asbestiform material, other samples contained a large percentage of rolled tale, tale shards, and chunky material (probably chlorite) E-GI 7/29 to 8/12 tale shards and ribbons were present; many additional samples contain various fibrous tales
JNJNL61_000064162; JNJNL61_000064161 (letter) [with sample key in JNJNL61_000006591]	12/31/1974	W. Windsor mill ore and ore noted as "used in cosmetic"	"Most of the 'fibrous' material was talc in one form or another"; fibrous talc in W. Windsor ore and talc specifically for use in cosmetics
JNJNL61_000043243 (letter); JNJNL61_000043244; JNJNL61_000043245; JNJNL61_000043246 [with sample key in JNJNL61_000006591];	7/1/1975	W. Windsor mill ore and ore noted as "used in cosmetic"	Indications of blocky talc and rolled talc Fibers rolled talc silicates: noted low and medium in HC (cosmetic) talc and WI (Windsor) talc; "silicate fibers," "fibrous talc," and "talc fiber" listed in HC and WI talc
JNJNL61_000027053	7/29/1975	W. Windsor ore	Some fibrous talc present
JNJ000065666	2/18/1976	Italian ore and Italian floated ore	2 samples contained talc ribbons, small rolled fibers of talc and talc chards; all fibrous type talc

Bates Number	Date	Location Found (Mine/Ore/Product)	Finding
IMERYS210824	4/26/1976	W. Windsor mill ore "industrial grade" and ore noted as "used in cosmetic"	21 samples were tested with some chrysotile and antigorite found as well as some fibrous F2-LI 11/24 to 12/8/1975: Platy talc with some talc fibers E2-LI 11/3 to 11/24/1975: Very platy, a few talc fibers H2-LI 12/22/75 to 1/5/75: Some platy, some talc fibers, some blocky K2-HC 1/26 to 2/13/76 - Play, few shards
JNJ000346747	6/2/1976	Johnson & Johnson Baby Powder talc	Sample 2 found some rolled talc and talc ribbons,  Sample 3 contained some fibrous talc but most of the sample consisted of platy talc  Sample 4 was mainly platy talc, but found some talc ribbons  Sample 6 showed some very fine talc ribbons  Sample 7 showed some small fibers all of which were talc
IMERYS210700	8/31/1976	Vermont 66 Talc	Higher Chlorite levels than normal found - current levels estimated at 1-3%
IMERYS210701	10/11/1976	Vermont 66 Talc	Higher Chlorite levels continued
JNJNL61_000043271 (letter); JNJNL61_000043272 [with sample key in JNJNL61_000006591]	12/2/1976	W. Windsor mill ore and ore noted as "used in cosmetic"	Talc ribbons and fibers; talc fibers; fibrous talc
JNJ000314406	2/22/1977	Italian "Val Chisone" Samples determination of fibers	Total fibers in Ray 3 - 82,000 fibers/g in Ray 4-5/0 Total fibers were 79,000/mg
IMERYS210810-210812	10/4/1977	W. Windsor mill ore and ore noted as "used in cosmetic"	40 talc samples tested some showed ribbons or fibers HC-M 4/4/77 to 4/16/77 - Fine ribbons some antigorite CI-R 3/14/77 to 3/21/77 - some shards present CI-X 4/25/77 to 5/2/77 - Some shards and ribbons CI-B 10/25/76 to 11/1/76 - Fibers and ribbons present CI-N 2/16/77 to 2/21/77 - Fine talc ribbons and shards

Bates Number	Date	Location Found (Mine/Ore/Product)	Finding
IMERYS210801-210803	10/5/1978	W. Windsor mill ore and ore noted as "used in cosmetic"	38 talc samples analyzed; some small chrysotile fibers found as well as some ribbons, shards, and fibrous talc  Aa 10/17 to 10/28 1977: Some rolled talc and talc shards  Ba 11/15 to 12/12/1977: Rolled talc and talc shards with some talc ribbons  Ea 1/3 to 1/13 1978: Only mineral "fibers" observed are talc rolls and shards  CA 12/5 to 12/16 1977: No mineral fibers other than talc shards and rolls  Fa 1/16 to 1/27 1978: Only material that appears fibrous is talc rolls and shards principally with one or two ribbons  Ga 1/30 to 2/11/1978: Some substantial talc needles  Ia 2/27 to 3/10/1978: Several ribbons and shards present
IMERYS210794	12/20/1979	Windsor mill ore and ore noted as "used in cosmetic"	18 samples submitted under R- 2612; Most of the samples had a few talc "ribbons" which were confirmed by selected area electron diffraction
IMERYS210788-210799	3/27/1980	Windsor mill ore and ore noted as "used in cosmetic"	Almost all of the samples consisted principally of very platy talc with probably fewer than average ribbons, shards or pseudo-fibrous particles.
IMERYS 210758	9/8/1980	W. Windsor mill ore and ore noted as "used in cosmetic"	19 Talc samples submitted, one sample TC-V had one fiber of chrysotile present
IMERYS210724	7/21/1983	W. Windsor mill ore and ore noted as "used in cosmetic"	7 monthly composite samples submitted all showed a fibrous clay (sepiolite) at small percentages
JNJ000281919 (letter); JNJ000281921	9/3/1992	Bulk samples	TEM from RJ Lee: 2 samples with small amount of fibrous talc
IMERYS 477879			Talc A99062: several fibrous structures displayed electron diffraction patterns indicative of talc (p 883)

Bates Number	Date	Location Found (Mine/Ore/Product)	Finding
JNJ000260807	Undated	Examination of J&J Italian talcs	Samples of Italian talc, one ground in Italy and one ground domestically were tested, fiber content of Italian ground talc less than 0.001% most of which is rolled talc, some fine fibers were also found, domestic ground talc contained more fibrous talc than Italian Ground
JNJ000269904	Undated	Final report on STS, Medicated Powder and Feminine Spray	Feminine spray had a few examples of rolled talc or other fibers, a few talc fibers were identified with electron diffraction  Medicated Powder: Few examples of fibrous talc and one fiber which could be considered suspect Shower-to-Shower: Fiber content quite low but showed rolled talc at 0.001% to 0.005% - 3 suspect fibers, a few talc shards were also found

Further, Dr. William Longo found fibrous talc in recent studies of Defendants' historical samples. In their January 15, 2019 report, Dr. Longo and Dr. Rigler reported that 54 of the 55 samples tested using the ISO 2262-1 PLM method contained fibrous talc, or 98%. The Blount/PLM method showed that 20 of 71 samples contained fibrous talc, or 28%.

Some, but not all, of these non-tabular talc grains were attributed to shape modification during the milling process rather than to natural causes (JNJ 000576631, JNJ000088746). In 1973, experiments conducted at CSMRI at the request of J&J showed that chrysotile asbestos could be altered to talc under conditions that could occur naturally (JNJ 000299336). It is likely, therefore, that some fiber-like talc grains may be natural pseudomorphs after a chrysotile component of original serpentinite. This pseudomorphic relationship is indicated for New England ultramafic rocks by Chidester (1968). A similar relationship between talc and earlier fibrous amphiboles has been known for at least a century (Hopkins, 1914). Hopkin's work contains photomicrographs that show talc partial replacement of anthophyllite as well as descriptions of a fibrous form of talc known as agalite said to be common in New York where it forms by the replacement of tremolite. The formation of fibrous talc from the partial or complete pseudomorphism of asbestiform anthophyllite or tremolite is suggested by Virta (1985), Ross (1968), and Stemple (1960). IARC has determined that fibrous talc (talc occurring in a fibrous habit) is a carcinogen to humans (IARC 2010, 2012).

#### C. GEOCHEMISTRY

The occurrence and geochemistry of heavy metals and arsenic are of concern in any talc ores used in products resulting in prolonged or repeated human contact. Permissible upper concentration limits were established in the 2 to 3 ppm range for As and 10 ppm for heavy metals reported as lead. Vermont serpentinite-related talc deposits contain elevated levels of certain heavy metals and arsenic (As). Repeatedly, tests suggest that Ni, Co, Cr, and As occurred in elevated amounts.<sup>19</sup>

Trace metal analytical data for early-use Italian ores are lacking. Analyses of Chinese talc ores consistently indicate very low concentrations of heavy metals (IMERYS 225295) with As, Co, Cr, and Ni values often at or below 1.2 ppm, 2.7 ppm, 4.0 ppm and 4.6 ppm, respectively (IMERYS 058214 at 226) in 2009, for example. Unless otherwise noted, the following element-specific discussions are with respect to Vermont serpentinite-related talc ores and products.

# 1. Arsenic

Arsenic is a known human carcinogen (IARC, 2012). Arsenic occurs in Vermont talc deposits in at least five primary minerals including gersdorffite (NiAsS), skutterudte (CoAs<sub>3</sub>), and cobaltite (CoAsS). A 1993 report also identifies As-bearing magnetite in ores of the Hamm mine which suggested that these and other sulfides-arsenides are the result of late secondary hydrothermal events. These minerals are not completely stable in a near-surface environment and tend to form secondary minerals. Annabergite, a secondary nickel arsenate, has been positively identified in several of the Vermont mines proving that arsenic is mobile there. Pitticite, an amorphous arsenic-bearing secondary material, has also been identified. The primary minerals are relatively dense and could tend to sink in a talc flotation circuit, concentrating with the other sink fractions. The fate of the secondary arsenic phases in the mill circuit is unknown. However, the level of soluble As clearly increases as ores containing primary As minerals are exposed to weather during pre-milling stockpiling (IMERYS 406170 at 176).

The acceptable arsenic content in talc for J&J's products has traditionally been quite low, ranging from 2 ppm to 3 ppm (IMERYS 058955 at 959 (2 ppm 1974); JNJ 000247362 (2 ppm 1976); IMERYS 104615 at 616 (2.5 ppm 1999); IMERYS 113402 at 412 (3 ppm 2004). Analysis of arsenic levels takes on particular importance given the chemicals historic and repeated documentation in Vermont mines. Notably, arsenic content of the float feed at the West Windsor plant routinely exceeded allowable levels (IMERYS 427235). It is unclear if the acceptable As levels are for total As or for that leachable by an arbitrarily chosen sample preparation technique. A comparison between total and "extractable" As is shown in the Skyline Labs 1998 report (IMERYS-MDL-AB\_0005560 at 583).

High arsenic in Argonaut mine ores required dilution with Hammondsville ore to reduce the overall As content in 1989. In 1990 an in-pit arsenic control plan was implemented at the Hamm mine that included mapping, visual evaluation, sampling and testing, and monitoring

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<sup>&</sup>lt;sup>19</sup> In 1976, it was determined that some of the nickel, cobalt, and chromium reported in talc analyses were not present in solid solution or substitution in the talc lattice but occurred in non-talc components (JNJ 000246467), making them potentially more biologically available.

(IMERYS 140630 at 632). The details of this program and its results are unknown. The critical nature of the arsenic content of talc ores was emphasized in 1990 by a study of the Rainbow mine. Regular sampling of ore showed arsenic contents ranging up to 158 ppm with many over 20 ppm (IMERYS 427235 at 244–247). Problems with the disposition of As in Argonaut stockpiled ore and the apparent oxidation of arsenic-bearing sulfides and arsenides, resulting in the release of soluble As, was clearly identified in the early 1990's (IMERYS 406170 at 176). West Windsor talc product exceeded 4 ppm As on five occasions in July and August of 1990 (IMERYS 427235 at 243). Plant feed during this same period varied from 5 ppm to 13.5 ppm As (IMERYS 427235 at 243). In a 1992 report, a series of 10 in-house arsenic studies, spanning the period 1982–1992, indicated elevated arsenic levels. Elevated arsenic levels were noted in the Hamm, Rainbow, and Argonaut, mines. (IMERYS 340050 at 090–117 (4/8/92 summary); IMERYS 3400050 at 098 (1/24/1991); IMERYS 340118 at 127 (6/4/1992); IMERYS 340118 at 119 (1/25/1993)).

Available data suggest that the required low As limits were not always maintained. For example, three samples of Grade 66 shear disc talc submitted in 2000 for testing by Chemex show total As values of 19, 11, and 10 ppm. The fate of this out-of-spec talc remains unclear. A 2006 Rio Tinto report on "Vermont Talc Ore" indicates an As content of 65 ppm (IMERYS-A 0002017).

Based on my review of the documents, it appears that the testing methodology for the presence of arsenic resulted in reported levels below those actually present. The potential influence of sample preparation (total digestion versus partial digestion) must be considered when examining the reported levels of arsenic and the heavy metals. For example, a comparison analysis of a yearly composite of Grade 66 talc using the J&J mandated method BPT 148 and a total digestion-inductively coupled plasma analysis resulted in 0.7 ppm and 2.0 ppm As respectively (IMERYS-A\_0015621). If only partial digestion preparation techniques are employed, then the arsenic levels could be underreported.

### 2. Nickel

High levels of nickel, a known human carcinogen (IARC, 2012), have been reported in testing of talc from the Hamm, Rainbow, and Argonaut mines – mines used to source talc for Johnson's talcum powder products.

In a mafic-ultramafic environment, Ni is often found in the lattice of mafic silicate minerals in substitution for magnesium. In this environment, Ni can also occur in the arsenide gersdorffite (see above) and the sulfides pentlandite (FeNi)<sub>9</sub>S<sub>8</sub> and violarite (FeNi<sub>2</sub>S<sub>4</sub>) (IMERYS 340118 at 119) and the arsenide niccolite (NiAs). (IMERYS 340118). One example of Nickel-bearing weathering products identified in Vermont talc is annabergite [Ni<sub>3</sub>(AsO<sub>4</sub>)3.8H<sub>2</sub>O)]. Annabergite is relatively easy to tentatively identify because of its green color and has been reported in ore from the Black Bear mine (IMERYS 340118 at 119 (1993)). Although the occurrence of gersdorffite at the talc mines is well documented, its fate during talc processing is unclear. Similarly, the fate of annabergite during talc processing is unknown, as is that of any other secondary or accessory minerals containing relatively abundant nickel. I have seen no evidence to suggest that Johnson & Johnson or Imerys ever planned or implemented a procedure for removal of nickel minerals from the talc ore.

According to J&J's corporate representatives, the maximum amount of allowable nickel in Johnson's talcum powder products was 5 ppm (Ex. 3, Hopkins deposition (2018)). Written specifications state that the maximum allowable nickel content is 10 ppm (JNJ 000629320). Despite these limits, nickel in concentrations exceeding 1500 ppm were reported in Vermont talc for decades, greatly in excess of the product specification limit.

Examples of results of Defendants' tests for nickel between the years 1972 and 2004 are as follows:

Bates Number	Date	Description	What Was Tested	Nickel
JNJ 000087928	10/1/1972	Baby powder	J&J 228P	1500 ppm
JNJ 000237379	12/31/1975	Ore & Concentrate	Stun A	1900 ppm/2500 ppm
JNJ 000238011	9/30/1976	Baby powder	Formula 34 Formula 499 Formula 499	1500 ppm, 1480 ppm, 1500 ppm
JNJ 000088570	2/12/1981	Omya Tale C-1 and Canada 1980 WTS	3 Samples *Analysis sent to J&J	2090 ppm, 2560 ppm, 2650 ppm
JNJ000285351	12/19/1988	Talcum powder	Sample (879-162)	2560 ppm
JNJ000246437	2/7/1990	talcum powder	Sample (90-53)	1940 ppm
JNJ000237076	10/1/1991	talcum powder	Samples No. (28005 & 28006)	1720 ppm/1942 ppm
JNJ000239723	6/1/1992	talcum powder	Sample (39-HV66)	2100 ppm
JNJ000239730	3/10/1994	talcum powder	Sample (93-HV66)	2260 ppm
JNJ000063608	3/13/1995	talcum powder	Sample (94-V66)	2070 ppm
JNJ000291914	7/16/1997	Grade 66	1996 Annual Composite Sample	247 ppm
IMERYS342524	9/22/1997	Grade 66	Annual Composite Sample	BPT 148 v. ICP 247 ppm v. 2490 ppm
JNJ000291916	3/9/1998	Grade 66	1997 Annual Composite Sample	2060 ppm
JNJ000347962	5/11/1998	Windsor 66	Non-Shear Disc Talc Sample	2190 ppm
JNJ000347962	9/24/1998	Windsor 66	Non-Shear Disc Talc Sample	2020 ppm
JNJ000347962	9/25/1998	Windsor 66	Non-Shear Disc Talc Sample	2020 ppm
JNJ000886067	2/9/1999	Grade 66	1998 Annual Composite Sample	2080 ppm
IMERYS- A_0015663	10/7/1999	Grade 66	5 Non-Shear Disc Talc Samples	1810-2190 ppm
IMERYS045184	2/21/2000	Grade 66	1999 Annual Composite Sample	2180 ppm
IMERYS045182	7/28/2000	Grade 66	3 Ore Samples	1890-2000ppm
IMERYS304036	9/26/2000	Grade 66	3 Non-Shear Disc Samples	2410-2510 ppm
IMERYS053387	2/21/2001	Grade 66	Composite Sample (A01055-1)	2190 ppm
IMERYS340454	2/7/2002	Grade 66	1999 Annual Composite Sample	2260 ppm

Bates Number	Date	Description	What Was Tested	Nickel
IMERYS340798	3/10/2003	Grade 96	2002 Annual Composite Sample	1980 ppm
IMERYS286445	1/5/2004	Grade 96	2003 Annual Composite Sample	2100 ppm

For the years 1974 to 2004, Grade 66 nickel content varied from 1300 ppm in 1976 (JNJ 000087928) to 2560 ppm in 1988 (JNJ 000285351) and 2510 in 2000 (IMERYS 304036). Concern over the potential effect of trace nickel in talc on allergic persons reached the point in 1994 that Luzenac proposed a study to evaluate this potentiality (IMERYS 210268 at 270). The results of such as study, if it was conducted, have not been disclosed. A series of analyses by Skyline Labs in 1988 indicates that 10-20% of the total Ni contained in these talcs is "extractable (IMERYS-AB 0005560 at 84).

Talc mined in Vermont had consistent, excessive levels of nickel, routinely exceeding 150 to 250 times the upper limit provided in J&J's specifications. This is troubling considering nickel is a known carcinogen (IARC, 2012).

#### 3. Chromium

Chromium is found in two forms, trivalent (III) and hexavalent (VI); hexavalent chromium is classified as a known human carcinogen by IARC and the U.S Environmental Protection Agency ("USEPA") (IARC 2006, 2012; USEPA 2014). It is also considered "reasonably anticipated" to be a human carcinogen by the National Toxicology Program (NTP) and a "potential occupational carcinogen" by the National Institute for Occupational Safety and Health (NIOSH) (NTP 2016; NIOSH 2012).

Chromium is a common constituent of serpentinites, occurring often as the mineral chromite, or otherwise associated with the similar mineral, magnetite. The association of Vermont's talc deposits with serpentinites suggests that high levels of chromium would be expected in some talc ores.

Vermont talc with chromium in excess of 200 ppm was known to J & J since 1976 (JNJ 000246467; JNJ 000245517). Examples of the results of Defendants tests for chromium, conducted between 1972 and 2004, are as follows:

Bates Number	Date	Description	What Was Tested	Chromium
JNJ 000087928	Oct-72	Baby powder	J&J 228P	190 ppm
JNJ 000238011	9/30/1976	Baby powder	Formula 34 Formula 499 Formula 499	185 ppm, N/A, 190 ppm
JNJ 000088570	2/12/1981	Omya Talc C-1 and Canada 1980 WTS *Analysis sent to J&J	3 Samples	Chromium: 194 ppm, 214 ppm, 305 ppm

Bates Number	Date	Description	What Was Tested	Chromium
JNJ000285351	12/19/1988	Talcum powder	Sample (879-162)	262 ppm
JNJ000246437	2/7/1990	talcum powder	Sample (90-53)	426 ppm
JNJ000237076	10/1/1991	talcum powder	Samples No. 28005 & 28006	277 ppm/251 ppm
JNJ000239723	6/1/1992	talcum powder	Sample (39-HV66)	328 ppm
JNJ000239730	3/10/1994	talcum powder	Sample (93-HV66)	457 ppm
JNJ000063608	3/13/1995	talcum powder	Sample (94-V66)	569 ppm
JNJ000291914	7/16/1997	Grade 66	1996 Annual Composite Sample	25.4 ppm
IMERYS 342524	9/22/1997	Grade 66	Annual Composite Sample	BPT 148 v. ICP 25.4 ppm v. 273 ppm
JNJ000291916	3/9/1998	Grade 66	1997 Annual Composite Sample	255 ppm
JNJ000347962	5/11/1998	Windsor 66	Non-Shear Disc Talc Sample	110 ppm
JNJ000347962	9/24/1998	Windsor 66	Non-Shear Disc Talc Sample	85.8 ppm
JNJ000347962	9/25/1998	Windsor 66	Non-Shear Disc Talc Sample	92.5 ppm
JNJ000886067	2/9/1999	Grace 66	1998 Annual Composite Sample	275 ppm
IMERYS- A_0015663	10/7/1999	Grade 66	5 Non-Shear Disc Talc Samples	85.8 -169 ppm
IMERYS045184	2/21/2000	Grace 66	1999 Annual Composite Sample	136 ppm
IMERYS045182	7/28/2000	Grade 66	3 Ore Samples	199-324 ppm
IMERYS304036	9/26/2000	Grade 66	3 Non-Shear Disc Samples	230-288 ppm
IMERYS053387	2/21/2001	Grade 66	Composite Sample (A01055-1)	110 ppm
IMERYS340454	2/7/2002	Grade 66	1999 Annual Composite Sample	223 ppm

Bates Number	Date	Description	What Was Tested	Chromium
IMERYS340798	3/10/2003	Grade 96	2002 Annual Composite Sample	245 ppm
IMERYS286445	1/5/2004	Grade 96	2003 Annual Composite Sample	284 ppm

Magnetic separation is used at several points in the talc processing flow path to remove magnetic minerals including chromite and associated magnetite. However, not all chromium-bearing minerals respond to magnetic separation and such minerals cannot be removed magnetically (JNJ 000246467; JNJ 000245517).

In addition to its occurrence in relatively stable oxides and within the talc lattice, Cr can also occur in other platy silicates such as chlorite family minerals, in extreme cases residing in "chrome clinochlore" or "kammererite." A chlorite called "chrome clinochlore" has been reported as a constituent of the deposit exploited at the Argonaut mine (mindat.org). The physical properties of the chlorites are similar to those of talc. Therefore, it would be expected for chromium-bearing chlorites to periodically reside in Vermont talc concentrate used in talcum powder products. Documents produced in litigation indicate that one or more unspecified chlorite species do occur as non-tale components in most analyzed tale products (see West Windsor analyses – IMERYS 213431; IMERYS 102508, as examples). The Cr content of these chlorites has not been determined precisely nor has the ratio of trivalent Cr(III) versus hexavalent Cr(VI). The Cr content of Grade 66 talc has been routinely reported in the 200 – 300 ppm range (IMERYS 045182 at 183, IMERYS 225184 and IMERYS 105215 at 226, for example), again far above the 5 ppm limit. Interestingly, there is a significant difference between the reported chromium content of Grade 66 talc when the sample has been prepared by J&J method BPT 148 versus the USP method which uses a total digestion technique. The levels reported using the USP method were much higher than the J&J method (IMERYS-A 0015621).

Internal documents outline J&J's concern regarding the potential carcinogenic nature of Cr(VI) (JNJ 000131758; JNJ 000131761; JNJ 000378044; JNJ 000378046). Imerys 035890 indicates that a sample of Vermont talc ore has 1700 ppm total Cr but <4 ppm Cr(VI). A 2010 J&J memo discusses raising the upper limit acceptable for total Cr to 7 ppm (JNJ 000131761 at 762). An accompanying memo also discusses the relationship between Cr(III) and Cr(VI). A discussion of the inhalation of hexavalent chromium is contained in this document. Regardless of valence, Grade 66 analyses consistently show Cr contents far in excess of 5, 7, or 10 ppm. Based on 14 reports of Grade 66 talc, during the period 1974 thru 2001 the Cr content varied from 569 ppm in 1994 (JNJ 000063611) to a low of 110 ppm in 1998 (LUZ015663 or IMERYS-A\_0015663).

# 4. Cobalt

Cobalt, classified as a 2B carcinogen by IARC (2012), is present in Vermont talc ore. in amounts approaching 100 ppm (76.2 ppm in 2001, IMERYS-A\_0015305; 92 ppm after total digestion of sample, 1997, IMERYS-A\_0015621; 62.4 ppm - 82.9 ppm, 1999, IMERYS-A\_0015663). Mineralogically, cobalt is reported to occur at the Johnson talc mine as both cobaltite

and skutterudite (see above). These minerals are dense and if unaltered to some secondary phase could accumulate with gersdorffite during the milling process. The presence of secondary Ni minerals strongly suggests that similar weathering paths might occur for the primary Co minerals. Since Co occurs in amounts equal to only about 5% of that of Ni, its secondary minerals could be relatively uncommon and overlooked, making it unlikely that they would be removed from the final product. If Co enters into the weathering cycle in a way analogous to annabergite, then its distribution in talc products could be complex and overlooked. Like Ni, it too appears to occur routinely in talc products in amounts exceeding the 3 ppm upper limit. Based on 12 composite samples, between the years 1974 and 2001 Grade 66 Co content ranged from a low of 56 ppm (1991-JNJ 000237076) to a high of 89 ppm (1998 IMERYS 304056).

Examples of the results of Defendants' tests measuring cobalt, conducted during the years between 1972 and 2004, are as follows:

Bates Number	Date	Description	What Was Tested	Cobalt
JNJ 000087928	10/1/1972	Baby powder	J&J 228P	50 ppm
JNJ 000238011	9/30/1976	Baby powder	Formula 34 Formula 499 Formula 499	57 ppm, N/A, 50 ppm
JNJ 000088570	2/12/1981	Omya Talc C-1 and Canada 1980 WTS *Analysis sent to J&J	3 Samples	84.4 ppm, 63.6 ppm, 73.8 ppm
JNJ000285351	12/19/1988	Talcum powder	Sample (879-162)	84 ppm
JNJ000246437	2/7/1990	talcum powder	Sample (90-53)	83 ppm
JNJ000237076	10/1/1991	talcum powder	Samples Nos. 28005 & 28006	56 ppm/57 ppm
JNJ000239723	6/1/1992	talcum powder	Sample (39-HV66)	63 ppm
JNJ000239730	3/10/1994	talcum powder	Sample (93-HV66)	67 ppm
JNJ000063608	3/13/1995	talcum powder	Sample (94-V66)	60 ppm
JNJ000291914	7/16/1997	Grade 66	1996 Annual Composite Sample	8.1 ppm
IMERYS 342524	9/22/1997	Grade 66	Annual Composite Sample	BPT 148 v. ICP 8.1 ppm v. 92 ppm
JNJ000291916	3/9/1998	Grade 66	1997 Annual Composite Sample	77.9 ppm
JNJ000347962	5/11/1998	Windsor 66	Non-Shear Disc Talc Sample	79.3 ppm
JNJ000347962	9/24/1998	Windsor 66	Non-Shear Disc Talc Sample	67.8 ppm
JNJ000347962	9/25/1998	Windsor 66	Non-Shear Disc Talc Sample	67.4 ppm

Bates Number	Date	Description	What Was Tested	Cobalt
JNJ000886067	2/9/1999	Grace 66	1998 Annual Composite Sample	72.9 ppm
IMERYS- A_0015663	10/7/1999	Grade 66	5 Non-Shear Disc Talc Samples	67.4-82.9 ppm
IMERYS045184	2/21/2000	Grace 66	1999 Annual Composite Sample	81.9 ppm
IMERYS045182	7/28/2000	Grade 66	3 Ore Samples	76.8-77.3 ppm
IMERYS304036	9/26/2000	Grade 66	3 Non-Shear Disc Samples	79 - 89ppm
IMERYS053387	2/21/2001	Grade 66	Composite Sample (A01055-1)	79.3 ppm
IMERYS340454	2/7/2002	Grade 66	1999 Annual Composite Sample	79.6 ppm
IMERYS340798	3/10/2003	Grade 96	2002 Annual Composite Sample	71.3 ppm
IMERYS286445	1/5/2004	Grade 96	2003 Annual Composite Sample	77.3 ppm

In summary, talc from Vermont deposits (approximately 1965-2002) used by Defendants for its talcum powder products contained elevated amounts of nickel, cobalt, and chromium. The test results as described above demonstrate that nickel, chromium and cobalt, known carcinogens, reach finished talc products in amounts above Johnson & Johnson's (J&J) specified limits.

### D. SAMPLING AND TESTING

The following paragraphs refer primarily to sampling and testing of talc-bearing materials with respect to asbestos minerals and potentially harmful trace metals and arsenic. Piecemeal and apparently incomplete data sets make it difficult to define and/or confirm sampling frequency, type, method, and even in some instances exact mine source of J&J talc over the past half century. The issue of sample representativeness is daunting when one considers that the United States personal care market for talc has been between 35,000 and 45,000 tons-per-year (tpy) with body powders somewhat less than 25,000 tpy (IMERYS 253265 at 266). Various documents outline sampling and testing protocols, an example of which is contained in the Windsor Minerals-Johnson and Johnson agreement of 1989 (JNJMX68\_000021632). As indicated in Ex. 60 of the Downey deposition for the Hammondsville, Hamm, and Argonaut mines, pre-milling sampling appears inconsistent and can contain analyses of varying media including drill core samples, infill samples, blast hole, and mine face samples.

In the case of Chinese talc, general specifications for Guangxi #1 and #2 crude ore sampling and testing were proposed (IMERYS-A 0015755; JNJ 000414760). Prescribed sampling

procedures are also given in a 2008 document (IMERYS 270594). Sampling and testing protocols for Chinese ores at the Houston port and processing facility are also given in a Rio Tinto Minerals 2008 document (IMERYS 036949). Ore sampling techniques do not suggest representativeness and were questioned in a 2009 Intertek audit (IMERYS 031712). A 2011 J&J Supplier Questionnaire indicates that ore is tested and approved prior to loading on ship for transport (IMERYS 042461 at 465). Sampling and testing protocols are given in an Imerys Talc document in 2013 (IMERYS 048750 at 861-862).

A similar document from 2009 indicates that chemical quality and "asbestos free guarantee" are required of the supplier (JNJ 000520884 at 886). A list of chemical parameters to be tested as described in this document does not include Cr, Co, or Ni. Testing prior to shipment is also generally described in IMERYS 037003 and IMERYS 041526. As recently as 2016, Chinese testing for asbestos is implied in a Guilin Guiguang Talc Development Company document (JNJ 000631362 at 364). Pier, in her 2018 deposition, states that the Chinese mine owner has always run J4-1 XRD analyses on ore shipments. However, I have not seen data confirming such testing. Examples of Certificates of Analyses show only major element chemistry and some specific physical properties. Sampling and testing of lump ore shipments reaching the United States are described in IMERYS 078694 at 695 and IMERYS 036999 at 7003.

In the broadest context of exploration and mining through beneficiation/milling and finally finished product preparation and packaging, sampling can be complex from the standpoint of frequency, timeliness, and lag time between sampling and receipt of final analytical data. A sample must be representative of the designated material regardless of what interval and point in the flow path it represents or else the resulting analytical data are of little value. Representativeness must be demonstrable and believable. Analytical data must be received in a timely manner or else they are of little value.

With respect to sample frequency, there are two separate issues: sampling during the mining process and sampling during the milling process. During the exploration/mine development/mining stages, drill core and drill cuttings can amount to many hundreds of individual samples and resulting analyses. An idea of the potentially large amount of sample data that was generated can be seen in the fact that at the Argonaut mine core drilling programs through 2008 resulted in 51,000 feet drilled during programs conducted in 1972, 1973, 1974, 1989, 1998, 2001, 2002, and 2007 (IMERYS441340). During this period additional infill drilling representing over 14,000 feet in 340 air rotary holes was sampled and "assayed" (IMERYS 238270). We have seen some ore characterization data of this sort with respect to the Hammondsville, Hamm and Argonaut mines, typically in terms of major mineralogical content and several specific trace metals and arsenic, but based on the limited amount of data produced, it appears that an adequate number of samples were not analyzed.

Similar data for samples taken on a routine basis as production progressed in the Argonaut and other relevant mines should likewise represent a large data set but are absent here. Production drill data do not seem to include asbestos (chrysotile or amphibole) testing, and in relation to drill cores taken at the Hamm mine, for example, Imerys did not sample talc ore intervals containing visible fibrous amphibole (IMERYS238270). This is contrary to all accepted sampling practices. In 2001, an effort was underway to locate and apparently resample some core and cuttings (IMERYS 237144 at 145), justification and need for this costly program was not stated. By 2006, all Imerys Vermont talc production was from a single open pit in the Argonaut mine that produced

about 150,000 tons of talc per year (none used for cosmetic purposes in the United States) (IMERYS499538). Serpentine and arsenic occurred near the edges of the ore zone and ore quality control by segregation at the mine site was inadequate (IMERYS 132823 at 825).

The second sampling frequency issue involves regular, scheduled or routine sampling at various points in the beneficiation or milling process and during the packaging of finished product. Incomplete data indicate that weekly composited flash dried talc samples were collected for J&J for asbestos analysis (IMERYS 139093 at 094; JNJ 000252225 at 226). A precise plan was presented for the West Windsor plant by Cyprus in 1992 that would have resulted in many hundreds of arsenic analyses per year (IMERYS 054579). Sampling protocols for ore and at many points along the processing line are described for the Windsor Minerals plant in 1988 (IMERYS 336098 at 147). However, there are no data to indicate that these aggressive plans were ever implemented. Similarly, with respect to As testing, in 1988, a program of daily ore testing as well as testing of daily composites of float feed and Grade 66 product was in place at the West Windsor mill (IMERYS 430707), another program that should have resulted in many reported analytical results, but the mechanism and frequency of sampling is unclear.

It is often unclear how and how frequently such sampling was actually done, especially in the period 1970 to 2000. An undated "Windsor Talc Topics" memorandum indicates weekly composites were taken (JNJ 000266813). A 1987 Windsor Minerals SOP document indicates XRD analysis for every two silos and TEM analyses every 6 months relative to asbestos determinations (exhibit 58 of Downey 8/8/18 deposition). Another Luzenac memorandum from 2001 indicates that daily samples of mill feed are collected and composited monthly for asbestos analysis (IMERYS 189001). A few documents indicate biweekly sampling of post-grinding Grade 66 product from storage silos in 1996 but there is no consistent series of analyses that would confirm such an ongoing sampling program (IMERYS 053275), although TEM analysis of quarterly composite samples during this period is described by Pier in her 2018 deposition.

A 2000 material specification sheet indicates that quarterly samples were to be composited annually for heavy metals analyses (JNJI4T5\_000005163 at 185). Monthly samples of ground ore are mentioned in 2001 as are quarterly composites of floated ore, but details of the sampling and compositing processes are lacking (IMERYS 237144). By 2003, quarterly samples of milled talc lots were to be sent to a single J&J authorized independent lab for full testing (IMERYS 093132 at 142). Quarterly sampling of finished talc lots for J&J by independent labs are mentioned relative to imported ores by the mid 2000's (IMERYS 114712 at 717 and IMERYS 093132 at 139). Despite these and other references to quarterly composite samples and annual composite samples of processed talc, details of the frequency that individual samples are taken that are composited, where in the process chain they are taken, how large they are, and how they are composited are often unclear or vague. The results of their analyses are, in some cases, lacking. Turnaround time for receipt of analytical results has at times be an issue as well (IMERYS 422182).

There is a lack of complete and consistent talc ore quality control data since at least 1970. For example, there should be at least 184 quarterly composite sample analyses for each milling site and at least 46 annual finished product analyses. These are in addition to routine data implied to have been collected during mine development and production activities, but data indicating that the sampling and testing was actually done is lacking or incomplete. Concern over sampling frequency is expressed in a 2003 email (JNJ 000389288). Normally expected failure or rejection rates were not observed, as discussed in detail in the expert report of Krekeler (2018).

The usefulness of annual after-the-fact composite sample testing is questionable. In this regard, lag time between sampling and testing is critical and the value of analyses performed years after the samples are taken is minimal as product derived from the sampled material is likely in the consumers' hands long before test results were available. An example of this is found in IMERYS 309892 at 895 where TEM analytical results for samples collected in October 2002 were not made available until January 2005.

Sample type is critical in dealing with ores that may have an inhomogeneous or variable mineral and trace element content such as those derived from talc deposits. It is inadequate to collect a single daily or hourly hand or grab sample from an ore stockpile in front of a crusher, or from a conveyor belt leaving a grinding circuit, and assume that this one sample or a composite, perhaps a kilogram in size, is representative of a day's production of several hundred tons. Saving such samples for a month, then crushing them and quartering them down to a manageable size is still only compositing samples that may or may not be representative of the material processed on the day the individual sample was taken. Such compositing can dilute the critical content of a single daily sample suggesting that for the month, all daily samples met quality standards. In general, details on how sampling was done are incomplete, other than with respect to Chinese lump ore once at an American port (IMERYS 199511 at 515, IMERYS 199801 at 802, IMERYS 270594 and IMERYS 532947). Continuous mechanical sampling resulting in material that can be composited into samples with a relatively high degree of representativeness has certainly been possible since the late 1960's. The use of such mechanical samplers was indicated for the Houston mill in the Pier deposition, but details were not given. Details of sampling and sample points are contained in an undated Luzenac document shown as exhibit 61 of the Downey deposition of 08/08/18. Automatic sampling is also mentioned in various descriptions of the West Windsor mill. For example, both grab and intermittent mechanical sampling was practiced at the West Windsor mill in 1998 (IMERYS 060623 at 629). The types and dates of implementation of mechanical sampling devices at both Houston and West Windsor is unknown. The use of automated sampling devices for Chinese talc was recommended without details in 2011 (JNJ 000133309).

Sample size becomes an important factor when one considers trace mineral and element content in an inhomogeneous medium. When the end product is variable in content and continuously produced in large quantity, even continuous sampling of extremely small percentages of that quantity does not insure representativeness. The continuous sample can weigh tens of pounds representing hundreds of tons of plant feed. The representativeness of this tiny fraction of the bulk sampled has not been demonstrated. The reduction of this large sample to a testable size while at the same time maintaining representativeness can be difficult. When one considers that the final sample to be analyzed in most instances will be only a gram or less (see for example IMERYS 113548 at 584 - Chinese sample for asbestos determination weighing 0.2349 gram and R. J. Lee Group reports of TEM analyses of samples weighing less than 10 milligrams), the issue of representativeness becomes obvious. For instance, in 1971, 20-ton truck loads of milled talc product were tested by the collection of a single one-pound sample drawn off the fluidized bed of the batch. That sample, representing 0.000025<sup>th</sup> of the batch, would then be reduced to a few grams or less for sample preparation and analysis. The potential for stratification or inconsistency in silo composition is not considered. Similarly, in 1971 four pounds of "representative feed" to the Vermont plant was said to be representative of a 24-hour composite of plant feed (JNJ000317664). There was no indication of the total tons the four pounds represented, how the sample was taken, and what precautions were taken to ensure representativeness. The Colorado School of Mines

Research Institute (CSMRI) recognized the sample size issue early in the 1970's, suggesting a preconcentration step to increase the opportunity for relatively small samples to yield data more representative of detectable amounts of trace constituents (see Reid report to Ashton of April 2, 1973 and JNJ 000268037). Pooley likewise was able to identify actinolite in Vermont talc using a concentrating technique in 1973 (Ex. J&J 47, Hopkins deposition). Similarly, a concentration technique was suggested by Dartmouth College for Vermont talc analyses in 1974 (J&J 58 1974 in Hopkins deposition). A preconcentration method to ensure the identification of small amounts of constituent accessory minerals was never adopted although J & J found it useful in reducing the detection limit for amphiboles by approximately one order of magnitude (JNJNL6\_000062982).

Analytical techniques fall into two categories- those that deal with the identification of individual minerals, particularly asbestos, and those that quantify trace element constituents. Although mineralogical analyses, protocols, methods and equipment have changed with time, Johnson and Johnson (and later Imerys) utilized the CTFA J4-1 method which employed XRD as the primary screening method of analysis for most minerals with a step scanning technique used for amphiboles. Enhanced XRD talc analysis was initiated by Cyprus in 1972 (IMERYS 205540) with a lower detection limit of about 0.5%. Because of possible peak interference by associated minerals, XRD was early on found to be unacceptable for determining the presence of small quantities of chrysotile. For the screening of talc for amphiboles, XRD with detection limits variously estimated in the tenths of a percent (e.g., 0.2% - IMERYS 205540), followed up with polarized light microscopy (PLM) if necessary, because of positive XRD results, was recommended by the Cosmetic Toiletries, and Fragrance Association (CTFA). This procedure was accepted by Rio Tinto protocol 2.34 (IMERYS 114712 at 713) and J&J (protocol 3.14) and used at least until 2004 (IMERYS 113402 at 435). Interestingly, in 1975 the CTFA allowed up to 0.5% fibrous amphibole in cosmetic talc (HHS00000001). The lower grain size limit for acceptable identification by PLM is 5 um; smaller fibers require Transmission Electron Microscopy (TEM) for identification.

For chrysotile, electron microscopy, initially Scanning Electron Microscopy (SEM) and later TEM were utilized. SEM offered the additional ability to gather chemical analytical data through energy dispersive spectrometry. TEM had the capability to perform electron diffraction analyses of individual particles. McCrone Environmental Services recommended TEM as the ultimate asbestos-in-talc analytical device in early 1987 (JNJNL61\_000040532). McCrone reports issued in 1983 indicate that the lower detection limit for asbestos by TEM was 0.1% (IMERYS 210707 at 725) suggesting that lower concentrations would go undetected if present. Five particles of the same asbestiform mineral were required for asbestos to be considered quantifiable. Amounts less than this were considered background or below detection limits. This suggests that something must be quantifiable if present, and this is not the case.

Cyprus Minerals began using in-house TEM for J&J asbestos analyses in 1989 and this was continued on by Luzenac America in 1992 (IMERYS 205540) and later Imerys (as discussed in the Pier deposition). TEM is considered to be able to detect a single asbestos fiber as small as 1 x 0.075 micrometers (IMERYS 210465). The shortcomings of these techniques are related to sample size, as small as 150 nanograms in some instances (IMERYS 209012; IMERYS 090928). In the case of both SEM and TEM, only small fractions of a gram are used. In the preparation of these samples, a concentration technique similar to the one recommended to J&J by the CSMRI

was not used. Thus, assurance that these tiny samples are representative of, in some instances, several tens of thousands of tons as in the case of annual composite samples, is not reasonable.

# Testing methodologies for asbestos were inadequate

The premise that talc products are free of asbestos is contrary to test result data and there is a misuse of the terms "absence of", "does not contain" and "none detected." None Detected does not necessarily mean not present or absent and using the terms interchangeably is a misnomer. In addition, there was an attempt to invoke "quantifiable" into the none present or none detected mix of terms as in 1995 by declaring that it took five or more asbestiform minerals of a single type in a single sample to be "quantifiable" (IMERYS 210465) and any fewer, although present, would go unreported. The determination of background levels by the use of blanks is discussed by Pier in her deposition. However, background was determined by the accepted ASTM method only once in Denver and never in the present TEM lab in San Jose, California, assuming that background would be the same in both labs and still at the 4 or 5 fiber level. However, an Argonaut certification report covering TEM analyses from 2001 – 2005 (Ex. IMERYS-5, Hopkins August 16, 2018) indicates that of 124 samples analyzed not a single amphibole fiber of either > 5 um or < 5 um was found, suggesting a background level of zero, making the presence of a single fiber significant and important. Single chrysotile fibers were reported in the same document in 21 samples; one sample contained two chrysotile fibers. These data suggest that for chrysotile background above one fiber is too high. Luzenac America product certification reports from the late 1990's use both "not detected" and "not quantifiable" for amphibole, chrysotile, and quartz with "not quantifiable defined as "mineral composition less than 0.1%" (see IMERYS 238445 at 447, for example). A Luzenac America technical report dated August 23, 2001 stated that less than four fibers identified by TEM would be reported as "none detected." Regardless, the specification for cosmetic talc as indicated in the Hopkins, Downey, and Pier depositions of 2018 is that the talc is asbestos free.

A sample with asbestos present at a level below a detection limit (even 1 fiber) cannot reasonably be interpreted as asbestos-free. An understanding of this potential problem is indicated by Imerys in 2004 (IMERYS 299320). In 2010 Luzenac changed the wording relative to asbestos from "free of" to "compliant" in terms of mandated upper limits (IMERYS 244543). "Absence of asbestos A" was still used in reporting in 2009 by contractor Intertek (IMERYS 113587 at 611). Chinese talc was certified by the Chinese as "does not have asbestos content" as late as 2012 (IMERYS 198884 at 886). Earlier, some Chinese ore was certified by Rio Tinto using the standard CTFA protocol (IMERYS 058042 at 073). Finally, an Imerys Talc Letter in 2013 states that "Imerys Talc is committed to assuring that our products manufactured in North America meet the most stringent regulatory and agency standards for asbestos. The standard is 0.1% as defined by regulatory agencies...." (IMERYS 027721). This, of course, suggests that an asbestos content of less than 0.1% is acceptable which is contrary to Defendants' policy that its products be asbestos-free.

In the case of trace metal analyses, there are two issues to consider. The first is sample preparation and the second is analytical technique. Relative to sample preparation in the laboratory, reduction in size to a relatively small amount by mechanical means is routine and apparently used in the analyses reported. Since the preferred and accepted analytical technique for most trace metals for decades beginning in the mid- 1960's was atomic absorption spectrophotometry (AA), the real issue was the sample dissolution aspect of preparation. In some instances, particularly those used by J&J, the total sample was not dissolved, and the resulting analysis reported only

partial metal contents. This understatement of total contained metals is illustrated in the comparison between the recommended J&J preparation protocol and a split run by commercial laboratory where the total sample was dissolved using a triple acid method followed by inductively coupled plasma analysis that resulted in much higher reported metal contents (IMERYS 352512 at 524). The argument that the short-term use of weak acids for partial solution as a means of best duplicating biological response is invalid in this situation. In the case of some arsenic analyses, a sample preparation technique was used that seems adequate for the determination of total arsenic in most samples. With respect to the metals distributed within individual mineral grains, analytical scans with an electron microprobe were used in some (but not all) cases and these results are considered accurate.

### III. CONCLUSIONS

Based on my review, it is my opinion to a reasonable degree of scientific certainty that the talc deposits that were used to source Defendants' talcum powder products (Italy, Vermont and China) contain fibrous talc, and chrysotile and/or fibrous amphiboles, all known human carcinogens. As to the Vermont talc deposits that sourced Defendants' talcum powder products, it is my opinion that the talc ore contained high levels of heavy metals including nickel and chromium, known carcinogens, and cobalt which has been classified as a possible human carcinogen.

It is my opinion that the selective mining practices employed by Johnson & Johnson and its suppliers, were inadequate to avoid ore or ore-related rock containing asbestos, fibrous talc, and heavy metals. Finally, Defendants' sampling and testing were insufficient to prevent these minerals from being included in the finished talcum powder products.

I may be asked to review additional materials and/or documents as the case progresses and, in that event, I reserve the right to supplement this report. My current hourly fee is \$150/hour for review of documents and related meetings and \$300/hour for testimony and related activities.

During the previous four years I have testified as an expert witness at deposition or trial in the following cases: Bean v. Alabama Power Company et. al (2013-2014); Fields v. (undisclosed mesothelioma litigation) (2014); Mauldin v. (undisclosed mesothelioma litigation) (2014).